IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAs) PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION**
THIS DOCUMENT RELATES TO:	:	**MDL No. 3094**
ALL ACTIONS/ALL CASES	:	**2:24-md-3094-KSM**

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' MASTER COMPLAINT

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I. INTRODUCTION

This multidistrict litigation ("MDL") involves claims brought by Plaintiffs who have been seriously injured by their use of drugs that, among other things, were designed, manufactured, marketed and sold by Defendants Novo Nordisk and Eli Lilly.[1] The drugs at issue are glucagon-like peptide-1 (GLP-1) receptor agonists (collectively, "GLP-1 RAs") which have become well known under their various brand names, including Ozempic, Wegovy, Saxenda, Victoza, Mounjaro, Zepbound and Trulicity. ¶ 1.[2] The GLP-1 RAs come with risks of significant injuries including: gastroparesis; bowel obstruction; necrotizing pancreatitis; gallbladder disease; aspiration of gastric contents and secondary complications such as micronutrient deficiencies; and Wernicke's encephalopathy. *See, e.g.*, ¶¶ 41-95.

Over the course of the past ten years, Defendants have transformed GLP-1 RAs from a novel medication approved for limited indications related to the treatment of diabetes to one of the most profitable drugs ever to reach market, drawing in countless patients with a promise of being a "magic pill" for weight loss. Defendants' rapid expansion of the market for GLP-1 RAs has had drastic results, growing the patient base to include many patients who would be better served choosing alternate treatments paths, whether competing diabetes medications or other weight-loss approaches, and who not only end up experiencing little to no clinical benefit from the drugs but

[1] Defendants Novo Nordisk A/S and Novo Nordisk Inc. are referred to collectively herein as "Novo Nordisk" or "Novo." The exclusion of additional Novo entities is covered by a stipulation between the Parties. *See* ECF 161. Defendants Eli Lilly and Company and Lilly USA, LLC are referred to collectively herein as "Eli Lilly" or "Lilly." Both Novo and Lilly are referred to collectively herein as "Defendants."

[2] Paragraph citations ("¶") herein refer to paragraphs in the Master Long Form Complaint and Demand for Jury Trial (ECF 294) ("Master Complaint" or "Complaint"). Mounjaro and Zepbound are combined GLP-1 and glucose-dependent insulinotropic polypeptide (GIP) receptor agonists (a "GLP-1/GIP RA") but are considered as part of the class of "GLP-1 RA" drugs. ¶ 149. "GLP-1 RAs" used herein includes GLP-1/GIP RAs.

also suffer significant injuries. As the Complaint explains in detail, GLP-1 RAs' ascension from a little-known diabetes medication to a blockbuster was not an accident, but the result of a calculated scheme that included spending hundreds of millions of dollars to: manipulate the medical community's views on obesity and obesity treatment; drive up demand through one of the largest and most invasive marketing programs ever seen; lower barriers to accessibility for the drugs (whether for their approved purposes or off-label); and push for governmental acquiescence in public reimbursement for these drugs.

Underlying this scheme was Defendants' consistent overstatement of the benefits and their downplaying of the risks of taking GLP-1 RAs. Ignoring a large swath of Plaintiffs' allegations and their import, Defendants, throughout their Brief,[3] assert that the Complaint "focus[es] principally on allegations that [Novo and Lilly] failed to adequately warn of certain side effects." Br. at 1. On the contrary, in addition to setting forth in detail the substantial evidence showing that Defendants were on notice that GLP-1 RAs caused significant injuries yet intentionally withheld that information from patients, their doctors, and the public; the Complaint alleges in detail Defendants' expensive and elaborate scheme, including a pervasive and comprehensive marketing campaign, to directly impact the behavior of patients and change physician prescribing habits.

The conduct alleged in the Complaint supports claims for relief under numerous theories that go well beyond a failure to warn claim. These claims are not, as Defendants suggest, "tacked onto their Complaint" or "extraneous to the core issues in the litigation." Br. at 1. Rather, the detailed facts alleged in the Complaint support many additional claims for relief, including breach of express and implied warranty, fraud (by misrepresentation and concealment), negligent

[3] The Memorandum of Law in Support of Defendants' Motion to Dismiss Plaintiffs' Master Complaint (ECF 329-1) is referred to herein as "Brief" or "Br." Defendants' Motion to Dismiss Plaintiffs' Master Complaint (ECF 329) is referred to herein as "Motion" or "Motion to Dismiss."

misrepresentation, statutory consumer protection claims for unfair trade practices, design defect, negligence, and negligent undertaking, among others. Individual Plaintiffs should be entitled to litigate all of the claims they may have, and to have all of their claims considered and ruled on, after full and fair discovery, and under the specific facts and state laws applicable to their claims.

Finally, Defendants raise numerous challenges that are fact-specific to each Plaintiff and others that would be subject to a state-by-state legal analysis. These are precisely the type of challenges that Defendants represented would not be part of the motion to dismiss process which was supposed to be focused on cross-cutting issues that could narrow the issues before the Court. These individual and state-specific challenges identified herein should be rejected.

Based upon the foregoing and as set forth below, Defendants' Motion should be denied.

II. BRIEF SUMMARY OF RELEVANT BACKGROUND

A. Summary of Factual Background

In 2010, the first drug of this class (Victoza®) was launched by Novo. ¶¶ 32, 127. Victoza® was not a blockbuster, though, as it was one of many options for treating type 2 diabetes in adults and it required a daily injection. Defendants then began to implement a grander plan for their GLP-1 RAs. Novo, and eventually Lilly, saw an opportunity to create, or tap into, a new market for weight loss drugs in the United States that had massive potential. ¶¶ 276-92.

Defendants embarked on a deliberate, strategic, and ultimately deceptive course to "medicalize" obesity, and to create and expand a massive, new market for GLP-1 RAs by directly influencing prescriber behavior. The Defendants invested money and effort in key opinion leaders, advocacy groups, and continuing medical education courses and scientific literature to further affect medical and public opinion. ¶¶ 317-69. Defendants engaged in some of the most aggressive, expansive, and expensive marketing of pharmaceutical drugs, including direct-to-consumer and unbranded advertising that made unprecedented use of online forums and digital platforms. ¶¶ 370-

402. Through these efforts, Novo achieved such a level of cultural saturation with Ozempic that it was being touted in the fall of 2022 by Variety magazine as "Hollywood's Secret New Weight Loss Drug," even though it was not approved for weight loss. ¶ 375. Defendants succeeded in creating a market for GLP-1 RAs that was expected to exceed $100 billion by 2030. ¶ 11.

To help achieve mass appeal for GLP-1 RAs, including those used off-label for weight loss, Defendants deliberately failed to provide full and fair information to prescribers and consumers about the safety of these drugs. Defendants intentionally downplayed and/or failed to disclose—in product labels and in advertising—many known and serious risks of taking these medicines including: gastroparesis and other gastrointestinal injuries, cyclical vomiting, gallbladder disease, bowel obstructions, ileus, esophageal injury, muscle wasting, dehydration, necrotizing pancreatitis, Wernicke's encephalopathy, pulmonary aspiration, and death. *See, e.g.*, ¶¶ 463-587.

In addition to concealing and downplaying these serious risks, Defendants intentionally omitted from their communications about these drugs to prescribers and consumers many other material facts, known to Defendants from their research and pharmacovigilance, that would have put the claimed benefits of the drugs in a more fair and accurate light, including, for example: (1) that the average person loses only a small percentage of their body weight while on GLP-1 RAs and all patients will plateau; (2) that GLP-1 RAs are not effective for everyone (*i.e.*, there are non-responders); (3) that patients gain back weight when they stop taking GLP-1 RAs (patients have to stay on the drug for the rest of their lives in order to have lasting benefit); (4) that weight loss achieved from GLP-1 RAs is not healthy weight loss and that when a person regains weight lost while on GLP-1 RAs, they are typically less healthy than when they began taking GLP-1 RAs; and (5) that many people stop taking GLP-1 RAs relatively quickly because of trouble tolerating the side effects of the drugs. ¶¶ 588-612. The non-responders or those who stop taking the drug in

short order will not lose weight on the drug but will still have the risk of injury.

The Complaint details the history of the development of the GLP-1 RAs, ¶¶ 29-40; the regulatory history, ¶¶ 107-54; the serious injuries and complications the drugs are known to cause, ¶¶ 41-95; how and when the Defendants became aware of the resulting serious injuries and complications, ¶¶ 155-256; and Defendants' extensive efforts to aggressively market and promote GLP-1 RAs, ¶¶ 276-433. It alleges that Defendants not only failed to warn physicians and consumers of the serious, known risks of these drugs, but Defendants intentionally and deceptively downplayed those risks, while overstating benefits and omitting material information about limitations on the supposed benefits of taking GLP-1 RAs. ¶¶ 434-612.

B. Relevant Procedural Background

This MDL was created by MDL transfer order dated February 5, 2024. ECF 1. Despite Defendants' repeated assertion that this case is "focused on alleged failure to warn," this case has, since its inception, involved broader issues including, but not limited to, "whether defendants made false, misleading, or incomplete representations regarding the safety of these products." ECF 1 at 1-2. At the Court's urging, the Parties reached agreement on a process for filing a Master Complaint, and the Court entered a scheduling order reflecting that agreement. ECF 300.

III. LEGAL STANDARD

"'To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *Starnes v. ThredUP Inc*., 2023 WL 4471673, at *2 (E.D. Pa. July 10, 2023) (Marston, J.) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation omitted)). "'A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Id*. (quoting *Iqbal*, 556 U.S. at 678). The plaintiff does not need to include "detailed factual allegations" but "provid[ing] the 'grounds' of his 'entitle[ment]

to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

In assessing the sufficiency of a complaint, courts engage in a three-step analysis: (1) identify the elements that must be pled to state a claim; (2) identify legal conclusions in the complaint not entitled to an assumption of truth; and (3) accept the well-pled factual allegations as true and determine if they plausibly state a claim. *Connelly v. Lane Constr. Corp*., 809 F.3d 780, 787 (3d Cir. 2016) (quoting *Iqbal*, 556 U.S. at 675). In step one, the Court need only consider the elements that have been challenged by the defendant. *See Lutz v. Portfolio Recovery Assocs., LLC*, 49 F.4th 323, 328-29 (3d Cir. 2022) (analyzing only the disputed element of plaintiff's claim). In step three, the Court must assume Plaintiffs' "factual allegations to be true, construe those truths in the light most favorable to the plaintiff, and then draw all reasonable inferences from them." *See Connelly*, 809 F.3d 790.

IV. ARGUMENT

A. Defendants' Motion to Dismiss Should Be Limited to Cross-Cutting Issues

Plaintiffs understood, based on Defendants' representations, that any motion to dismiss attacking the Master Complaint would be limited to "crosscutting issues that can narrow the scope of the litigation" and would specifically ***not*** involve challenges "state by state or a 50 state survey in this round of motions." 11/25/24 Tr. at 6:7-9, attached hereto as Exhibit "A"; *see also* 3/14/24 Tr. at 51:19-22, relevant excerpts attached hereto as Exhibit "B" ("I think we take your Honor's guidance on ***not raising issues at the motion to dismiss process that might be one-off state law issues***. So we are probably not inclined to do that." (emphasis added)). Defendants took a decidedly different approach in the Motion, challenging claims whose viability may turn on individualized facts that could be asserted in any given Plaintiff's Short Form Complaint and claims whose viability varies based on each jurisdiction's law. These issues are not typically appropriate for

motions to dismiss a master complaint in the MDL setting, where a court should consider such a motion "to the limited extent that it challenges the sufficiency of the factual allegations common to all Plaintiffs." *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 2012 WL 3582708, at *4 (N.D. Ill. Aug. 16, 2012).

1. The Master Complaint Is Appropriately Labeled an Administrative Complaint (Defendants' Motion to Strike Should Be Denied)

The Master Complaint expressly states in the Introduction that it is an administrative tool, not an operative pleading. Defendants move to strike this statement, Br. at 4, 37-39, yet agree with Plaintiffs that the Master Complaint ***in combination with*** the Short Form Complaint creates the Operative Complaint, Br. at 37-38. Defendants also agree that "no individual cases are 'merged or consolidated,'" Br. at 38 n.11. Defendants argue that the Parties should be clear with respect to the "'intent and significance' of master pleadings" but gloss over the fact that there are essentially two choices: either the master complaint is a consolidated complaint (where the individual cases are merged into one), or it is an administrative complaint (where the cases keep their separate identity). *See, e.g.*, *In re Refrigerant Compressors Antitrust Litig.*, 731 F.3d 586, 589-90 (6th Cir. 2013). Where the individual cases are not "merged" or "consolidated," as Defendants concede they are not (and cannot be, given the range of state laws and claims at issue in the MDL), it is an administrative complaint.[4] *See, e.g.*, *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, 2020 WL 7418006, at *7 n.6 (D.N.J. Dec. 17, 2020) (citing *In re Refrigerant*, 731 F.3d at 590); *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 2012 WL 3582708, at *3 (master complaint is a "procedural device"); *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 141-42 (E.D. La.

[4] "Merger" or "consolidation" is more likely to occur in the context of MDL litigation where multiple class actions have been filed by numerous representative plaintiffs who then, after transfer for pretrial coordination, file a "consolidated class action complaint" that supersedes all other complaints and becomes the operative complaint.

2002) (same); *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 454 (E.D. La. 2006) (master complaint is an "administrative device"); *In re Digitek Prods. Liab. Litig.*, 2009 WL 2433468, at *8 (S.D. W. Va. Aug. 3, 2009) (referencing "administrative nature" of master complaint).

Defendants express concern that labeling the Complaint "administrative" means that the Court's rulings with respect to cross-cutting issues will not allow for dismissal of any claims "with any finality," thereby creating inefficiency. Br. at 38-39. But the law is clear that "[c]ases consolidated for MDL pretrial proceedings ordinarily retain their separate identities" meaning that for an order to "qualify under § 1291 as an appealable final decision," it must "dispos[e] of ***one of the discrete cases*** in its entirety." *Gelboim v. Bank of Am. Corp.*, 574 U.S. 405, 413 (2015) (emphasis added); *see also Home Depot USA Inc. v. LaFarge North America Inc.*, 59 F.4th 55, 61 (3d Cir. 2023) (relying on *Gelboim*, noting "'a district court's decision whether to grant a motion . . . in an individual case depends on the record in that case and not others.'"); *In re Nat'l Prescription Opiate Litig.*, 956 F.3d 838, 845 (6th Cir. 2020) ("Nor can a party's rights in one case be impinged to create efficiencies in the MDL generally."). There may be a different procedure for the Court to apply cross-cutting rulings with respect to a master complaint to individual cases within an MDL, but that does not change the "administrative" nature of this Master Complaint.

Nor does it mean that the Master Complaint process is not creating efficiencies in other ways. As part of the compromise in the MDL that resulted in the Master Complaint and (still pending) Short Form Complaint process, Defendants have been relieved of their obligation to answer, have set up a process where they receive core information quickly from each individual Plaintiff through a Plaintiff Fact Sheet, and have successfully argued to address certain issues labelled as "cross-cutting" early in the litigation.

Defendants' Motion to Strike, Br. at 37-39, should be denied because, as noted above,

Defendants agree that the Master Complaint is not one that merges individual cases, *i.e.*, it is not a consolidated complaint. *See generally Curbio, Inc. v. Miller*, 2023 WL 2505534, at *2 (E.D. Pa. Mar. 13, 2023) (noting that motions to strike are disfavored) (Marston, J.). In addition, labeling the Master Complaint as "administrative" is not "redundant, immaterial, impertinent, or scandalous." *See* FRCP 12(f). As the Sixth Circuit indicated when describing the difference between an administrative complaint and a consolidated complaint, "[t]o ward off confusion, lawyers might do well to make plain what they have in mind when they use the label 'master complaint.'" *See In re Refrigerant*, 731 F.3d at 590. That is precisely what Plaintiffs did here.

2. It Would Be Inappropriate to Decide Fact-Intensive and State-Specific Challenges on this Motion

Many MDL courts are reluctant to entertain motions to dismiss master administrative complaints because the facts are ultimately supplemented by short form complaints that bring the facts and pertinent state law into focus, allowing for a more complete review of the merits. *See, e.g.*, *In re Nuvaring Prods. Liab. Litig.*, 2009 WL 4825170, at *2 (E.D. Mo. Dec. 11, 2009) ("the transferee court typically does not rule on cumbersome, case-specific legal issues"); *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 2012 WL 3582708, at *4. Indeed, individual Plaintiffs here will adopt and incorporate by reference some or all of the Master Complaint through the Short Form Complaint process. At that time, the two documents taken together will become the Operative Complaint. For this reason, it makes little sense to argue that the Master Complaint is legally deficient due to its failure to include certain individualized factual allegations or because some indeterminate state law differs in its scope and application from that of another state.

One reason for this reluctance is on display here. Nearly all of Defendants' claim-specific challenges involve nuances in state law that require complex choice-of-law analyses as well as a determination of the appropriate legal standards in a given state. When sitting in diversity, federal

courts must apply the substantive law of the states. *See Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). When determining the law of a given jurisdiction, federal courts are bound by the rulings of state supreme courts, but in the absence of a controlling state supreme court decision, courts must make an *Erie* guess by looking to other sources of authority including decisions of state intermediate and appellate courts, "'analogous decisions, considered dicta, scholarly works and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand.'" *Spence v. ESAB Group, Inc.*, 623 F.3d 212, 216-17 (3d Cir. 2010) (quoting *Norfolk S. Ry. Co. v. Basell USA Inc.*, 512 F.3d 86, 92 (3d Cir. 2008)).

Where there are claims from every jurisdiction, performing an *Erie* analysis requires substantial work that cannot be done on abbreviated briefing without articulated challenges to the law of specific jurisdictions, particularly when no cross-cutting efficiencies are realized through that process. No Plaintiff's claim under a jurisdiction's law should be short-changed in this process simply because Defendants singled out a few states that they argue, with little analysis, do not permit a viable claim for a given set of facts. Each state has developed its own common-law precepts that deserve appropriate attention before the Court makes an *Erie* prediction. And, the law of any given jurisdiction could be highly fact-dependent, further counseling restraint in ruling on these matters until the facts of a given Plaintiff's case are before the Court. For these reasons, the Court should reject Defendants' fact-specific and state-by-state challenges identified below.

B. Plaintiffs' Breach of Express Warranty Claims Are Plausibly Pled

The inefficiency of Defendants' approach is apparent in their challenge to Plaintiffs' breach of express warranty claim (Count III). The only challenge Defendants make to this claim is that the representations alleged by Plaintiffs—that Defendants' GLP-1 RAs were "safe and effective"—do not, as a matter of law, rise to the level of a warranty. Br. at 8-11. As a preliminary matter, this is a state-specific inquiry that should not be considered on this Motion. Defendants

note that "courts have required plaintiffs to identify whether and how their states' law departs from the generally applicable U.C.C. rule barring such claims." Br. at 10 n.3. That type of varied analysis is exactly what the Parties intended to defer and is inappropriate for this Motion.

Nonetheless, Defendants challenge Plaintiffs' claim on three grounds, arguing that: (1) promoting a drug as "safe and effective" cannot constitute an express warranty as a matter of law, (2) statements like "safe and effective" never constitute express warranties under the U.C.C., and (3) omissions are not express warranties. Br. at 8-11. Each of these arguments should be rejected.

1. Plaintiffs' Allegations Regarding Defendants' Multi-Faceted Safety Representations Constitute an Express Warranty

Relying on a single case decided under New Jersey law, Defendants assert that a plaintiff cannot, as a matter of law, assert an express warranty claim based upon a representation on the label of a prescription medication that it is "safe and effective." *See* Br. at 9-10 (citing *In re Avandia Mktg., Sales Pracs. & Prods. Liability Litig.*, 588 F. App'x 171, 174 (3d Cir. 2014) ("*Avandia*")). But the GLP-1 RAs' labels are not the sole basis of Plaintiffs' express warranty claims as they were in *Avandia*. 588 F. App'x at 178 (noting representations were "in one source—Avandia's 'labels and packaging'"). Here, Plaintiffs allege that Defendants' representations were made in numerous and varied ways to Plaintiffs and their prescribing physicians, including by the Defendants' "websites, advertisements, promotional materials, and through other statements." ¶ 687; *see, e.g.*, ¶¶ 309-56, 370-426, 588. As the Third Circuit noted in *Avandia*, other courts have permitted express warranty claims regarding safety and efficacy to proceed where the representations were made in places ***beyond the label itself***, including in articles, at conferences, and in journals presented to the medical community. *See Avandia*, 588 F. App'x at 178 (citing *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 602, 625-26 (E.D. Pa. 2008) (representations in "'various articles, conferences, and journals presented to the medical community'") and *Simonet v. SmithKline*

Beecham Corp., 506 F. Supp. 2d 77, 88-89 (D.P.R. 2007) (representations in numerous sources)).

Here, Plaintiffs allege throughout the Complaint that Defendants promoted their drugs' safety through a multi-faceted, multi-pronged approach made in multiple settings. Plaintiffs allege that Defendants made specific statements as to the safety and efficacy of their GLP-1 RAs. *See, e.g.*, ¶¶ 108, 113, 116, 138, 309, 327, 352, 372, 280. Defendants made these statements with respect to their GLP-1 RAs as treatment for chronic weight management even before the drugs were approved for that purpose. *See, e.g.*, ¶¶ 351, 380, 385, 403-15. In addition, Plaintiffs allege that:

> Defendants engaged in a multipronged approach to control and manipulate the universe of knowledge around GLP-1 RAs and obesity treatment ***including, but not limited to making direct payments to doctors, many of whom were influential in the relevant disciplines, so that they would promote the use of GLP-1 RAs; writing, promoting or funding articles regarding the safety and efficacy of the GLP-1 RAs; speaking at conferences regarding the safety and efficacy of GLP-1 RAs***; participating in and influencing health care advocacy groups focused on obesity and obesity treatment; conducting continuing medical education seminars related to GLP-1 RAs; and spending millions of dollars lobbying for prescription drug coverage of GLP-1 RAs.

¶ 309 (emphasis added); *see also* ¶¶ 317-26, 347-51, 352-56. The Complaint then provides more specific allegations describing each of Defendants' activities. ¶¶ 310-69; *see, e.g.*, ¶¶ 317-26 (key opinion leaders speaking on national television programs); ¶¶ 345-51 (continuing medical education aimed at prescribing physicians and health care providers); ¶¶ 352-56 (scientific literature aimed at researchers and health care providers); ¶¶ 370-85 (direct-to-consumer marketing); ¶¶ 386-402 (extensive online marketing campaigns); ¶¶ 403-15 (promoting off-label use); ¶¶ 416-30 (partnering with telehealth providers). These are examples of affirmations or promises by Defendants, upon which Plaintiffs relied—what is required for a breach of express warranty claim. *See, e.g.*, *Wells v. Johnson & Johnson*, 554 F. Supp. 3d 1207, 1212 (W.D. Okla. 2021) (applying Oklahoma law, citing authorities applying Arizona and New York law); *Gremo v. Bayer Corp*., 469 F. Supp. 3d 240, 257-58 (D.N.J. 2020) (applying New Jersey law); *Baudin v.*

AstraZeneca Pharms. LP, 413 F. Supp. 3d 498, 510-12 (M.D. La. 2019) (applying Louisiana law).

Courts have repeatedly held that similar allegations are sufficient to state a claim for express warranty in cases involving pharmaceutical marketing. For instance, like the plaintiffs in *Knipe*, Plaintiffs allege that Defendants represented GLP-1 RAs as safe and effective in "various articles, conferences, and journals presented to the medical community." 583 F. Supp. 2d at 625-26; *see also Suttman-Villars v. Argon Med. Devices, Inc.*, 553 F. Supp. 3d 946, 957 (D.N.M. 2021) (permitting express warranty claim that medical device was safe and effective based on manufacturer's "advertising and promotion of the [device] constituted an affirmation, promise, or even a description"). Other district courts have even permitted express warranty claims to proceed based on allegations that the manufacturer "expressly warranted" that the drug was "safe and effective," "overstated the efficacy," and represented that the drug "was as safe or safer, and as effective or more effective" than alternatives. *See Sellers v. Boehringer Ingelheim Pharms., Inc.*, 881 F. Supp. 2d 992, 1010-11 (S.D. Ill. 2012); *see also Lee v. Mylan Inc.*, 806 F. Supp. 2d 1320, 1327 (M.D. Ga. 2011) (permitting express warranty claim where plaintiff alleged defendants "made affirmations of fact or promises regarding the safety and effectiveness" of fentanyl patches); *Simonet*, 506 F. Supp. 2d at 89 (permitting express warranty claim where plaintiff alleged that defendant "represented, in package inserts, prescribing information, the PDR, and other marketing literature distributed to physicians, patients, and the general public that PaxilCR is of merchantable quality, fit, effective, safe, and otherwise not injurious to the health and well-being of patients"). Given the weight of authority holding that similar allegations are sufficient to state a breach of warranty claim, Plaintiffs have stated a claim for breach of express warranty.

2. Plaintiffs Allege Misrepresentations of Fact, Not Opinion

Next, Defendants argue that the alleged misrepresentations of their drugs' safety and efficacy were mere "opinion" and therefore, do not support an express warranty claim under the

Uniform Commercial Code. Br. at 9-10. Defendants are mistaken in their argument that Plaintiffs' misrepresentation claims and representations of safety and efficacy are mere puffery. The question of whether a representation is mere puffery or creates a warranty is a question of fact. *See Overstreet v. Norden Lab'ys, Inc.*, 669 F.2d 1286, 1290 (6th Cir. 1982) ("The trier of fact must determine whether the circumstances necessary to create an express warranty are present in a given case."); *see also Ebin v. Kangadis Food Inc.*, 2013 WL 6504547, at *3 (S.D.N.Y. Dec. 11, 2013) (citing *McDonnell Dougals Corp. v. Thiokol Corp.*, 124 F.3d 1173, 1176 (9th Cir. 1997) ("whether seller affirmed a fact amounting to an express warranty is a question of fact")). The inquiry revolves, in part, around whether the seller has made representations on something about "'which the buyer is ignorant, or whether he merely states an opinion or expresses a judgment about a thing as to which they may each be expected to have an opinion and exercise a judgment.'" *Overstreet*, 669 F.2d at 1290-91 (citation omitted).

Here, Defendants expressly represented their GLP-1 RAs as safe for specific uses, such as improving glycemic control, reducing cardiovascular risks, and aiding chronic weight management, and did so in a variety of ways.[5] ¶ 686; *see, e.g.*, ¶¶ 310-430. These safety representations are factual statements about Defendants' products, made by the manufacturers of these products, who unquestionably have knowledge superior to that of Plaintiffs or their physicians; putting the representations well within the realm of fact, and far from mere opinion or puffery.[6] These are also the type of safety representations that other courts have found to be an

[5] By contrast, in the cases that Defendants rely on, the plaintiffs made only general assertions of the drug's safety and efficacy. *See* Br. at 10 (citing *Barrett v. Tri-Coast Pharmacy, Inc.*, 518 F. Supp. 3d 810, 829 (D.N.J. 2021) (granting motion to dismiss where plaintiff failed to allege any specific representations by the defendant and only recited the elements of the claim); *Horsmon v. Zimmer Holdings, Inc.*, 2011 WL 5509420, at *4 (W.D. Pa. Nov. 10, 2011) (dismissing case where plaintiffs did not identify specific statements warranting the product as safe and effective)).

[6] Defendants' reliance on the express warranty claim in *Bjorklund v. Novo Nordisk A/S*, 705 F.

"affirmation of fact." *See, e.g., Johnson v. Eisai, Inc.*, 590 F. Supp. 3d 1053, 1064 (N.D. Ohio 2022) (finding plaintiff stated a claim for breach of express warranty where the defendants represented the drug "was effective as a weight loss adjunct, was safe for use in that way, and its effectiveness outweighed its risk.").[7] In addition, courts have consistently held that similar representations of a product's safety and efficacy are more than mere opinion, particularly where, as here, they were disseminated through medical literature and continuing medical education targeting potential prescribers. *See Johnson v. Johnson & Johnson*, 2024 WL 3202336, at *2 (E.D. La. June 27, 2024) (Defendants' statements in advertising that their "baby powder goes through a 'strict 5 level safety process, ensuring every ingredient is safe for use'" and "'possesses specified characteristics or qualities,' *i.e.*, safety and purity" are such that they "go beyond a 'general opinion' or 'general praise' that a product is safe and effective."); *Williamson v. Stryker Corp.*, 2013 WL 3833081, at *9 (S.D.N.Y. July 23, 2013) (". . . statements that the knee device was safe and effective - made directly by Defendants' employees and on the website - are not simply 'opinion or commendation' of the product.").

3. Plaintiffs Allege Breach of Warranty Based on Affirmative Representations, Not Omissions

Defendants' final argument ignores the allegations in the Complaint and is premised on the false assertion that Plaintiffs' express warranty claim is based merely on a failure to warn. *See* Br.

Supp. 3d 636, 643 (W.D. La. 2023) is misplaced. That dismissal, which was without prejudice, applied to a complaint that alleged "the product was advertised in some capacity as safe for its intended use," and did not include allegations like those here of specific instances across various media where Defendants falsely promoted the drug as safe for its intended and off-label use.

[7] The Court in *Johnson* also distinguished *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 818 (N.D. Ohio 2004), relied upon by Defendants. Br. at 10; *see Johnson*, 590 F. Supp. 3d at 1064. *In re Meridia* was decided on summary judgment and the court ruled, among other things, that plaintiffs did not provide *evidence* of the breach of express warranty where they relied on general references to advertisements. 328 F. Supp. 2d at 818-19.

at 11. To be clear, Plaintiffs do not base their breach of express warranty on Defendants' omissions, but rather their affirmative representations as to the safety of the drugs. *See* Section IV.B.1, *supra*. Defendants' citation to *Sidco Prods. Mktg., Inc. v. Gulf Oil Corp.*, 858 F.2d 1095, 1099 (5th Cir. 1988), is inapposite as that was a summary judgment decision applying Texas law where the plaintiff based its breach of express warranty claim on defendant's omissions. Br. at 11. Here, Plaintiffs' claim is based on Defendants' affirmative statements made through various outlets to patients, healthcare providers, and the public regarding the safety of their drugs. *E.g.*, ¶¶ 309, 317-26, 347-56; *see also Knipe*, 583 F. Supp. 2d at 625-26; *Suttman-Villars*, 553 F. Supp. 3d at 957.

C. Plaintiffs' Breach of Implied Warranty Claims Are Plausibly Pled

Plaintiffs also plausibly allege claims for breach of implied warranty. Plaintiffs sufficiently allege that Defendants' GLP-1 RAs were not fit for their ordinary purpose or use because they caused serious and dangerous injuries. *See, e.g.*, ¶¶ 155-225; ¶¶ 717-19. This is a straightforward implied warranty claim. *See, e.g., In re Hair Relaxer Mktg. Sales Pracs. & Prods. Liab. Litig.*, 702 F. Supp. 3d 692, 705-06 (N.D. Ill. 2023) (finding plaintiffs sufficiently alleged warranty claims by alleging that product did not perform as intended and resulted in serious injuries).

Beneath this general synthesis, however, the law governing breach of implied warranty claims varies by jurisdiction. At each turn, Defendants use phrases such as "in some jurisdictions," "other states," and "[f]or those states," Br. at 12-14, reflecting what is obviously true—that implied warranty is not a cross-cutting issue. There is broad agreement among courts that this type of attack on implied warranty claims is inappropriate given the variation in states' laws. *See In re Hair Relaxer*, 702 F. Supp. 3d at 706 ("[t]his Court will again not parse state law variations at this stage of the case"); *In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.*, 537 F. Supp. 3d 679, 721 (D.N.J. 2021) ("*Allergan Biocell*") (refraining from deciding plaintiff-specific questions when considering a motion to dismiss a master complaint); *In re Testosterone Replacement*

Therapy Prods. Liab. Litig., 2014 WL 7365872, at *9 (N.D. Ill. Dec. 23, 2014) ("Without delving into the specifics of different states' laws, plaintiffs have sufficiently pled claims for breach of the implied warranty of merchantability."); *In re Recalled Abbott Infant Formula Prods. Liab. Litig*., 2023 WL 3585639, at *11 (N.D. Ill. May 22, 2023) ("[T]he Court will not grapple at this point with issues of particular states' law[.]"); *In re Nuvaring Prods. Liab. Litig.*, 2009 WL 4825170, at *2 (E.D. Mo. Dec. 11, 2009) ("Not only would each state's substantive laws pertaining to particular claims need to be reviewed but each state's conflicts of law rules would need to be analyzed.").

Nonetheless, Defendants raise six discrete arguments purporting to call into question Plaintiffs' breach of implied warranty claims: (1) there is a broad prohibition against these claims for prescription products, Br. at 11; (2) Plaintiffs do not allege any specific GLP-1 RA does not conform "to other goods sold as such," *id*. at 11-12; (3) some states' product liability laws subsume these claims, *id*. at 12-13; (4) some states apply the learned intermediary doctrine to bar these claims, *id*. at 13; (5) some states require privity for these claims, *id*.; and (6) Plaintiffs' allegations are conclusory, *id*. at 13-14.[8] None of these arguments warrants dismissal.

Broad Prohibition. Defendants contend that "implied warranty claims cannot be brought against prescription medication manufacturers under the present circumstances." *Id*. at 11. This is incorrect. In fact, courts routinely allow implied warranty claims against pharmaceutical manufacturers. *See, e.g., Vanderwerf v. SmithKlineBeecham Corp.*, 414 F. Supp. 2d 1023, 1026 (D. Kan. 2006) (permitting implied warranty of merchantability claim against drug manufacturer); *DeCostanzo v. GlaxoSmithKline PLC*, 643 F. Supp. 3d 340, 353-54 (E.D.N.Y. 2022) (same);

[8] Defendants make a seventh argument—that Plaintiffs cannot "maintain a claim by invoking the implied warranty of fitness" because the purported use "must differ from the usual and ordinary use of the goods" and the presence of a physician means Plaintiffs did not "rel[y] on the seller's judgment." Br. at 12. Plaintiffs are not asserting such a claim, so Defendants' arguments fail.

Simonet, 506 F. Supp. 2d at 88 (same).

Conforming to Other Goods. Defendants misstate what Plaintiffs must allege to sustain this claim. Defendants erroneously summarize U.C.C. § 2-314 as requiring allegations that the goods do not conform "to other goods sold as such," as specifically limited to the exact type of goods (*i.e.*, other GLP-1 RAs). *Id*. Defendants cite no authority for that proposition, and for good reason. States do not require such pleading, but rather only allegations that the product did not perform as warranted. *See, e.g.*, *Yachera v. Westminster Pharms., LLC*, 477 F. Supp. 3d 1251, 1268 (M.D. Fla. 2020) ("The implied warranty is designed to 'protect the purchaser by allowing it to obtain the benefit of the bargain, thereby placing it in the same position it would have been in if the product had functioned properly.'") (quoting *Step-Saver Data Sys., Inc. v. Wyse Tech.*, 1990 WL 87334, at *4 (E.D. Pa. June 21, 1990)). Plaintiffs have sufficiently alleged that Defendants' GLP-1 RAs were not of merchantable quality given the severity of injuries Plaintiffs suffered for which Defendants had not disclosed the risk or the full extent of the risk. ¶¶ 155-225.

Subsumption. Defendants again rely on state law variance, referencing potential limitations on the claim in "some jurisdictions," Br. at 12, but do not meaningfully engage with any of those state laws or demonstrate why wholesale dismissal of Plaintiffs' implied warranty claims is appropriate. For example, while some state PLAs provide the exclusive vehicle to plead all theories of liability, including implied warranty, Plaintiffs acknowledge as much in the Complaint and will cite to those statutes as appropriate in Short Form Complaints. *See* ¶ 727 (noting existence of state PLAs and preserving right to all claims under them as permitted). Whether any state's PLA applies is a question that needs to be determined on a Plaintiff-specific, fact-specific, and state-law specific basis. *See In re Smitty's/CAM2 303 Tractor Hydraulic Fluid Mktg., Sales Pracs., & Prods. Liab. Litig.*, 2022 WL 710192, at *29 (W.D. Mo. Mar. 9, 2022)

(finding Kansas PLA does not subsume a claim for unjust enrichment). Defendants' attacks on pleading under the various state PLAs is discussed in Section IV.H, *infra*.

Learned Intermediary. Defendants overstate the applicability of the learned intermediary doctrine to preclude Plaintiffs' claims again without considering each state's laws. Numerous states have permitted warranty claims to proceed notwithstanding the learned intermediary doctrine. *See, e.g.*, *Wholey v. Amgen, Inc.*, 86 N.Y.S.3d 16, 18 (1st Dep't 2018) ("The learned intermediary doctrine does not compel dismissal of the claims that the drug's warning labels were insufficient, since the claims are premised not on defendants' failure to warn plaintiff directly but on their failure to provide proper warnings to her prescribing medical professionals."); *Sellers v. Boehringer Ingelheim Pharms., Inc.*, 881 F. Supp. 2d 992, 1006 (S.D. Ill. 2012) ("[T]he plaintiff has alleged that BIPI failed to adequately warn physicians regarding the risks of Pradaxa and that BIPI concealed material risk information from physicians. Accordingly, assuming the plaintiff's allegations are true, the learned intermediary doctrine does not shield BIPI from liability."). Further, Plaintiffs have alleged that Defendants failed to provide adequate warnings that would permit the learned intermediary doctrine to apply. *See Smith v. Boehringer Ingelheim Pharms., Inc.*, 886 F. Supp. 2d 911, 924 (S.D. Ill. 2012) (if "a warning is inadequate and the risk is not widely-known within the medical community, the learned intermediary doctrine does not shield the manufacturer from liability."); *see, e.g.*, ¶¶ 345–49 (Defendants promoting their drugs through continuing medical education aimed at prescribers); ¶¶ 350–51 (Defendants presenting at industry and academic conferences to promote their drugs); ¶¶ 463–76 (Defendants' labels, warning, and prescribing information failing to warn patients or prescribers of serious adverse injuries). To the extent the Court considers it at this stage, the learned intermediary doctrine does not stand as an obstacle to Plaintiffs' breach of implied warranty claims.

Privity. Defendants overstate the applicability of state privity requirements, citing the law of five states. Br. at 13. Other cases have allowed implied warranty claims under the law of the very same states due to factual circumstances and applicable exceptions. *See Allergan Biocell*, 537 F. Supp. 3d at 743-50 (permitting implied warranty claims under Alabama, Arizona, California, Florida, Georgia, Idaho, Indiana, Kentucky, Michigan, Nevada, New York, Ohio, Tennessee, and Washington law despite privity requirements); *see also In re Hair Relaxer*, 702 F. Supp. 3d at 706 ("As Plaintiffs point out, some states have exceptions to the privity requirement. This Court agrees with the approach in other MDL cases in this district declining to rule on these state-specific issues at this stage[.]"). Defendants do not attempt to discuss the law of any of these states, leaving the Court with no hook to hang any cross-cutting ruling.

Conclusory Allegations. After raising the panoply of state-specific challenges, Defendants make a rote assertion that Plaintiffs' allegations are conclusory. Br. at 13-14. Defendants also assert that Plaintiffs did not identify every potential state-law permeation of the elements of an implied warranty claim when making their conclusory allegations. *Id.* at 13-14.

As the moving party, Defendants must, at a minimum, identify what elements of Plaintiffs' claims are inadequately pled. Without such guidance, Plaintiffs cannot guess at the deficiencies Defendants contemplate. Plaintiffs can, however, state that ¶¶ 708-29 set forth an array of allegations specific to implied warranty that satisfy the state law variations for breach of implied warranty. In addition, taking the Complaint as a whole and considering the facts pled throughout, Plaintiffs have set forth voluminous allegations of fact to support each element of a breach of implied warranty claim. *See, e.g.*, ¶¶ 41-106 (not safe and fit for ordinary purpose); ¶¶ 155-256 (knowledge of Defendants); ¶¶ 309-402 (defendants warranting to physicians and patients, etc.).

D. Plaintiffs Have Plausibly Pled Claims for Fraud and Misrepresentation

1. Rule 9(b) Does Not Apply to Claims Beyond Plaintiffs' Fraud Claims

In an effort to impose a heightened pleading standard, Defendants impermissibly seek to recharacterize a number of Plaintiffs' claims as "sound[ing] in fraud." Br. at 14. Defendants do not explain or offer citation to any authority that would explain what classifies a cause of action as one that "sounds in fraud" but this effort, if successful, would group six different causes of action together—Counts V, VI, VII, VIII, IX, and X—including various levels of misrepresentation under every jurisdiction's law as well as the unfair trade practices and consumer protection laws of 55 states and territories (*see, e.g.*, ¶ 758). Grouping these causes of action together under the banner of "fraud" is improper and serves only to muddy the issues.

Plaintiffs do not dispute that their fraud claim (Count V) is governed by Rule 9(b). But, there is significant authority stating that negligent misrepresentation claims are not typically subject to Rule 9(b). *See Anderson v. Battersby*, 2024 WL 3498352, at *5 (M.D. Pa. July 22, 2024) ("the weight of authority [in the Third Circuit] suggests that Rule 9(b) does not apply to negligent misrepresentation claims") (citing *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 829 (E.D. Pa. 2016); *Tricontinental Indus., Ltd. v. PricewaterhouseCoopers, LLP*, 475 F.3d 824, 833 (7th Cir. 2007) ("[Negligent misrepresentation] is ***not*** governed by the heightened pleading standard of Rule 9(b)." (emphasis in original)); *CNH Am. LLC v. Int'l Union, United Auto., Aerospace & Agricultural Implement Workers of Am. (UAW)*, 645 F.3d 785, 794-95 (6th Cir. 2011) (assessing a negligent misrepresentation claim solely under Rule 8(a)); *Smallwood v. NCSOFT Corp.*, 730 F. Supp. 2d 1213, 1231 (D. Haw. 2010) ("A negligent misrepresentation claim does not require intent, and accordingly is not subject to Rule 9(b)."); *Ronpak, Inc. v. Elecs. for Imaging, Inc.*, 2015 WL 179560, at *4 (N.D. Cal. Jan. 14, 2015) ("negligent misrepresentation claims are not subject to Rule 9(b).").

Similarly, courts have been reluctant to apply the heightened pleading standard in Rule 9(b) to statutory unfair trade practices and consumer protection claims. *See, e.g., State of Fla., Off. of Atty. Gen., Dep't of Legal Affs. v. Tenet Healthcare Corp.*, 420 F. Supp. 2d 1288, 1310 (S.D. Fla. 2005) (FDUTPA claim did not need to be pled with particularity); *Pelman ex rel. Pelman v. McDonald's Corp.*, 396 F. Supp. 2d 439, 445 (S.D.N.Y. 2005) (claim for deceptive practices under New York's consumer protection statute is not subject to Rule 9(b)); *U.S. ex rel. Polied Envtl. Svcs., Inc. v. Incor Group, Inc.*, 238 F. Supp. 2d 456, 463 (D. Conn. 2002) (Rule 9(b) "does not govern" the pleading of Connecticut Unfair Trade Practices Act claims); *Summit Elec. Supply Co., Inc. v. Int'l Bus. Machines Corp.*, 2008 WL 11451895, at *3 (D.N.M. Mar. 31, 2008) ("[E]xtending Rule 9(b) to a claim under the UPA would be inconsistent with Tenth Circuit case law."); *Bald v. Wells Fargo Bank, N.A.*, 688 F. App'x 472, 476–77 (9th Cir. 2017) ("No heightened pleading standard applies in this case, where the allegations are sufficient under the 'unfair' prong."); *Crisp Hum. Cap. Ltd. v. Authoria Inc.*, 613 F. Supp. 2d 136, 139 (D. Mass. 2009) ("Indeed, to the extent it does not involve fraud, a Chapter 93A claim is not subject to a heightened pleading requirement."). Defendants provide no compelling reason for the Court to extend the reach of Rule 9(b) beyond the limits set by courts in their respective states.

2. Plaintiffs' Fraud Allegations Satisfy Rule 9(b)

As to the claims where Defendants assert that Rule 9(b) may apply, Defendants again mischaracterize or flatly ignore vast swaths of allegations in arguing that Plaintiffs have not pled the who, what, when, where, and how of Defendants' fraud. Br. at 15-16. "The purpose of Rule 9(b) is to provide notice, not to test the factual allegations of the claim." *Morganroth & Morganroth v. Norris, McLaughlin & Marcus, P.C.*, 331 F.3d 406, 414 n.2 (3d Cir. 2003). Defendants cannot seriously contend that Plaintiffs' allegations leave them in the dark about the nature of the claims that Plaintiffs assert or the time, place, and location of the alleged fraudulent conduct.

As an initial matter, the specific allegations supporting each Plaintiff's fraud claims will inevitably vary based on the information about the GLP-1 RAs that reached each Plaintiff. Each Plaintiff will have an opportunity in the Short Form Complaint to set out those individual facts and identify the state-specific claims they are bringing. Determination of these claims is not a cross-cutting issue and should not be decided on this Motion.

Process aside, Plaintiffs' fraud claim is well pled. Importantly, Plaintiffs' fraud claim is based on omissions—that Defendants possessed information with respect to the safety and testing of the GLP-1 RAs that they knew was material to Plaintiffs yet intentionally concealed that information, which, if known, would have prevented Plaintiffs from using these drugs. ¶¶ 730-48. Courts have "relaxed" the heightened pleading standard in Rule 9(b) in the context of fraudulent omissions. *See, e.g.*, *Majdipour v. Jaguar Land Rover N. Am., LLC*, 2013 WL 5574626, at *15 (D.N.J. Oct. 9, 2013); *Oak Plaza, LLC v. Buckingham*, 2023 WL 2537661, at *17 (D. Md. Mar. 16, 2023) ("the Fourth Circuit held earlier this year that a plaintiff pleading fraud by omission or concealment is subject to a 'relaxed Rule 9(b) standard.'"). "This is because 'a plaintiff in a fraud by omission suit will not be able to specify the time, place, and specific content of an omission as precisely as would a plaintiff in a false representation claim.'" *Id.* (quoting *Falk v. Gen. Motors Corp.*, 496 F. Supp. 2d 1088, 1098-99 (N.D. Cal. 2007)); *see also In re Takata Airbag Prod. Liab. Litig.*, 193 F. Supp. 3d 1324, 1337 (S.D. Fla. 2020) ("By definition, Plaintiffs cannot point to one particular statement by [defendant] as this count is for an omission—a non-statement.").

Here, Plaintiffs allege specific facts that Defendants concealed: that their GLP-1 RAs were unreasonably dangerous because of the increased risk of various injuries and that the GLP-1 RAs "had not been adequately and/or sufficiently tested for safety." ¶ 732; *see, e.g.*, ¶ 733; *see also* ¶ 267 (discussing inadequate testing on drugs that are marketed off-label). The Complaint also

contains extensive allegations of Defendants' intentional omission of risks in their marketing materials. *E.g.*, ¶ 588. Plaintiffs allege specific facts that Defendants' concealed: (1) the average person only loses a small percentage of their body weight while on GLP-1 RAs; (2) GLP-1 RAs are not effective for everyone; (3) patients regain the weight when they stop taking GLP-1 RAs (*i.e.*, they have to stay on the drug forever); (4) the weight loss achieved while on GLP-1 RAs is not a healthy weight loss; (5) when a patient regains the weight loss achieved while on GLP-1 RAs, they are typically less metabolically healthy than when they began the drug; and (6) many people stop taking GLP-1 RAs relatively quickly due to difficulty tolerating the drugs. ¶¶ 589-612.

In addition, Plaintiffs allege where these facts could have or should have been disclosed—where Defendants or their representatives were promoting the safety and efficacy of their GLP-1 RAs, through key opinion leaders, in the literature aimed at health care providers, marketing materials to physicians, direct-to-consumer marketing, and online marketing campaigns. *See*, *e.g.*, ¶¶ 309-433, 589; *see also* ¶¶ 317-19 (Novo's key opinion leader speaking on "60 Minutes" and Oprah); ¶¶ 347-49 (continuing medical education aimed at doctors); ¶¶ 350–51 (presentations at industry and economic conferences); ¶¶ 352-56 (academic literature and research); ¶¶ 371–75 (Novo's large-scale direct-to-consumer marketing); ¶¶ 379–84 (Lilly's large-scale direct-to-consumer marketing); ¶¶ 386–402 (Defendants' extensive online and social media marketing).

Plaintiffs also allege that Defendants engaged in off-label marketing in which they concealed the lack of adequate testing for such off-label uses. For example, Plaintiffs allege that Novo launched its first television advertisement on July 30, 2018, where the ad stated Ozempic may help patients lose weight, ¶ 372; on February 12, 2023, Lilly aired an advertisement promoting Mounjaro, saying "people taking Mounjaro lost up to 25 lbs," ¶ 384; Novo's Ozempic website promoted the drug's efficacy at weight loss across several years and on various website pages, ¶

409; Lilly promoted Mounjaro for weight loss on its website, ¶ 414; and both Novo and Lilly promoted off-label use, ¶¶ 410, 415. Plaintiffs point to specific statements over several years on various platforms. *See, e.g.*, ¶¶ 371, 384, 410, 414, 415. And, the Complaint contains allegations related to off-label promotion. *E.g.*, ¶¶ 403–30.

Courts have repeatedly found similar allegations to satisfy Rule 9(b). *See, e.g., Nelson v. Nissan North Am., Inc.*, 894 F. Supp. 2d 558, 567-69 (D.N.J. 2012) (fraud by omission claim satisfied Rule 9(b) when the complaint alleged defendant knew of information and withheld it, defendant had exclusive knowledge or information about the problem, the information was material, plaintiff relied on the materiality of the non-disclosed information, and resulting damages); *Houston v. Bayer Healthcare Pharms., Inc.*, 16 F. Supp. 3d 1341, 1350 (N.D. Ala. 2014) (heightened pleading standard satisfied by alleging product "comes with package label that warns about certain dangers" and that information was omitted from label); *Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 885-86 (N.D. Cal. 2013) (allegations that defendant "concealed and misrepresented the health risks associated with off-label applications" satisfied heightened pleading standard).

By contrast, Defendants rely on cases where plaintiffs referenced generalized misstatements as opposed to the specific statements in various media, as Plaintiffs allege here. Br. at 16-17. For example, in *King v. Ethicon, Inc.*, 2022 WL 2341633, at *6 (D.N.J. June 29, 2022), the plaintiff failed to plead the contents, place, manner, or timing of the misrepresentations. *See also Blair v. Johnson & Johnson*, 2020 WL 1172715, at *6 (W.D. Ky. Mar. 11, 2020) (dismissing negligent misrepresentation claim under Rule 9(b) where "[t]he complaint only mentions vague representations" that the defendants "misrepresented the safety and efficacy of the Products."); *Hernandez v. Johnson & Johnson*, 2021 WL 320612, at *5 (E.D. Wash. Jan. 8, 2021) (generalized

facts not "'accompanied by the who, what, when, where, and how of the misconduct charged'" and "'Plaintiff [did not] attempt to make any argument that they are.'") (*quoting Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir 2003)). In another case, Plaintiffs failed to include essential facts. *See Gross v. Coloplast Corp.*, 434 F. Supp. 3d 245, 252-53 (E.D. Pa. 2020) (finding that "facts are missing" and suggesting that counsel should do "sufficient investigation and research to ascertain facts" which was "not unreasonable because there are many cases making the same claims," etc.).[9]

Defendants claim that "Plaintiffs' innocent misrepresentation claim [Count X] fails for the same reason" with no further explanation or citation to any state's law. Br. at 17. However, not only are the omissions set forth above sufficient for the reasons discussed, Plaintiffs also allege numerous, specific misrepresentations made consistently by Defendants as well as specific time frames discussed below with respect to Plaintiffs' non-fraud claims. For example, Plaintiffs identify with specificity both written and oral statements made by Defendants that are false and misleading. *See, e.g.*, ¶ 372 (Novo's first television advertisement for Ozempic touting weight loss even though it was not approved for weight loss); ¶ 384 (Lilly's first television advertisement for Mounjaro touting weight loss even though it was not approved for weight loss); ¶ 409 (Novo promoting Ozempic for weight loss on its website); ¶¶ 414-15 (Lilly promoting Ozempic for off-label use); ¶ 590 (specific representations by both Defendants overstating weight loss); ¶ 595 (Defendants marketing GLP-1 RAs as a "metabolic reset").[10]

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[9] The facts recited by the court in *Bentley v. Merck & Co.*, 2017 WL 2349708, at *2 (E.D. Pa. May 30, 2017), are much more rudimentary than the facts alleged here. In addition, the Court here does not have the benefit of individual factual allegations that will be provided in the Short Form Complaints and specific state law upon which to evaluate the fraud by omission claims.

[10] Defendants' authorities with respect to "Plaintiffs' innocent misrepresentation claim" are inapposite. Br. at 17; *see Smith v. Bank of America Corp.*, 485 F. App'x 749, 753 (6th Cir. 2012) (not sufficiently pled where fraudulent statement was made orally and subject to Statute of Frauds

Defendants' arguments with respect to alleging the "where" of the fraud focus on the allegations in a single paragraph, while ignoring specific allegations throughout the Complaint. Br. at 17. First, as noted above, denoting the specific "where" in the context of an omission is a "relaxed standard" because, by definition, no statements were made. *See, e.g.*, *Oak Plaza, LLC*, 2023 WL 2537661, at *17-18. Notwithstanding that fact, Plaintiffs alleged numerous places where material facts could have been disclosed as discussed above; the Complaint has an entire section dedicated to Defendants' various online or digital platforms, any one of which could have served as a place for disclosure of the omissions. *See, e.g.*, ¶¶ 386-402; *see also* ¶¶ 592, 595. With respect to misrepresentations, Plaintiffs have done much more than make "general references to advertisements and statements," as Defendants contend. Br. at 17. Rather, they have identified specific advertisements, websites and other places where Defendants made fraudulent statements. *See, e.g.*, ¶¶ 371, 384, 410, 414, 415, 590. This is sufficient, as numerous courts have held. *See, e.g.*, *Cowen v. Lenny & Larry's, Inc.*, 2017 WL 4572201, at *4-5 (N.D. Ill. 2017) (Rule 9(b) satisfied when plaintiff alleged misstatements were contained on defendant's "website and the packaging"); *Kunneman Properties, LLC v. Marathon Oil Co.*, 2019 WL 4658362, at *4 (N.D. Okla. Sept. 24, 2019) (alleging misrepresentations on "monthly check stubs from September 1, 2011 to present (when and where)" satisfied Rule 9(b) even though "the specific dates of the monthly check stubs are not alleged" because "specific dates are not necessary to provide notice of the nature of the fraudulent scheme"); *State Farm Fire & Cas. Ins. Co. v. Jun Shao*, 2020 WL 3429036, at *3 (N.D. Okla. June 23, 2020) (alleging fraud "during the insurance application process" satisfied Rule 9(b) because it sufficiently notified defendants of fraud claims).

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and thereby inadmissible); *S. Track & Pump, Inc. v. Terex Corp.*, 623 F. Supp. 2d 558, 567 (D. Del. 2009) (specific time of fraud was insufficiently pled when given general month-long time frames).

Defendants' final argument – that Plaintiffs group Defendants together – also fails. As noted previously, the Complaint contains voluminous allegations, some of which refer to "Defendants" collectively because both Defendants engaged in that activity collectively. Further, some allegations specify actions taken individually by each Defendant, Novo and Lilly. For example, with respect to off-label marketing, ¶¶ 403-15 address Defendants' promotion of their GLP-1 RAs for off-label use, but ¶¶ 404-11 make specific allegations regarding Novo while ¶¶ 412-15 make specific allegations regarding Lilly.

Plaintiffs' fraud, misrepresentation and other deceptive act claims are alleged in the same manner. Plaintiffs identify the individual actions Defendants took in perpetuating their fraud by differentiating between, among other things, the Defendants' websites, advertisements, and funding of key opinion leaders. ¶¶ 371, 384, 410, 414, 415. This is all that is required. *See In re Arizona Theranos, Inc., Litig.*, 256 F. Supp. 3d 1009, 1028 (D. Ariz. 2017), *on reconsideration in part*, 2017 WL 4337340 (D. Ariz. Sept. 29, 2017) (finding plaintiffs sufficiently pled fraud by omission by pointing to defendants' "representative samples of websites, press releases, statements to the press, direct order forms, and other marketing materials").

3. The Court Should Not Dismiss Plaintiffs' Fraudulent / Intentional Misrepresentation Claim

Count VI of the Complaint is a placeholder so that: (1) individual Plaintiffs can add facts in their Short Form Complaint to support a fraud claim if appropriate under the facts of their individual case, or (2) it can be added as part of an amendment after discovery if warranted. *See* Compl., Count VI, n.544. Defendants' Motion, Br. at 19, should be denied with respect to fraudulent / intentional misrepresentation because the Short Form Complaint will provide an avenue for individuals to assert such a claim based on the facts of their case and otherwise.

4. Plaintiffs' Misrepresentation Claims Are Plausibly Alleged Under Any Standard

Plaintiffs' misrepresentation-based claims (Counts VIII-X) are sufficiently pled under Rule 8. As outlined above, Rule 8 requires only that a complaint contain sufficient factual matter, which if accepted as true and providing all reasonable inferences to the plaintiff, states a plausible claim for relief. *See Starnes*, 2023 WL 4471673, at *2. Here, the Complaint contains voluminous and detailed factual allegations, not conclusory statements, that support Plaintiffs' misrepresentation claims. Even so, Defendants challenge one element of Plaintiffs' misrepresentation claims—whether Plaintiffs have identified any actionable omissions or misrepresentations beyond mere "generalized assertions." Br. at 19-20. As set forth above and herein, Plaintiffs have satisfied their pleading burden.

In addition to the numerous omissions and misrepresentations that have been pled with particularity to satisfy Rule 9(b) as discussed above, the Complaint details Novo and Lilly's additional misrepresentations about the drugs' efficacy, safety, and approved uses. Plaintiffs allege that Defendants spent millions of dollars promoting their GLP-1 RAs for weight loss even though they were not approved for that purpose. ¶¶ 372, 383, 405–15, 612. Plaintiffs allege that users' actual weight loss is significantly—and measurably—lower than that represented by Defendants. For example, Novo represented a 15% weight loss for users when only 18% of Novo's semaglutide users reported a weight loss of 15% after one year of treatment.[11] ¶ 590. Instead, on average, users

[11] Defendants note that there is no number identified in ¶ 590 as the misrepresented number. Br. at 20. Clearly the first sentence of ¶ 590 is truncated but importantly, for the Court's reference, the context of ¶ 590 reveals the substance of the allegation that Defendants overstated weight-loss. *E.g.*, ¶ 590 ("Only 18% of those on semaglutide reported a weight loss ***of at least 15%*** of their body weight after one year of treatment.") (emphasis added). In addition, the Complaint is replete with specific allegations related to the Defendants' overstatement of the amount of weight patients may lose—Novo (¶¶ 237, 372, 409, 851-54) and Lilly (¶¶ 380, 383-84, 414-15, 856). Discovery will reveal the precise weight-loss representations made by Defendants in different forums.

lost just 3.6% to 5.9% of their body weight. *Id*. In addition, a significant percentage of users, about 14%, failed to meaningfully respond to the drug, meaning they lost less than 5% of their body weight (and one-third lost less than 10% of their body weight). ¶¶ 102, 591. Plaintiffs make similar allegations regarding Lilly whose results for tirzapetide users were similar. ¶ 591.

Defendants also have misrepresented the long-term efficacy of the drugs. Contrary to Defendants' marketing, the drugs do not result in sustained weight loss for most users. When patients stop taking the drugs, the vast majority regain most of the weight within one year and regain all the weight within five years. ¶¶ 99-101, 590, 592, 595. Only a small percentage of users sustain their weight loss over a four-year period. ¶ 590. Similarly, Lilly's study of tirzepatide showed that users regained 14% of their body weight after discontinuing the drug and maintained only about 10% of their weight loss. ¶ 596. At the end of the study, participants' weight gain was on an upward trajectory; in other words, patients were gaining weight back even while taking the drug. *Id*. And, to be clear, the representations were being made when the GLP-1 RAs at issue were not approved for weight loss. *See, e.g.*, ¶ 409 (Novo); ¶¶ 414-15 (Lilly).

Defendants contend that the allegations about Defendants' misrepresentations concerning the long-term efficacy of the drug are implausible, "because common sense dictates that a patient stops receiving the benefits of a medication when she ceases treatment." Br. at 21. But Novo has marketed its drugs as "metabolic resets," implying long-term benefits and that users will be able to keep the weight off on their own after ending treatment. ¶¶ 593–95. And it is hardly "common sense" that the "treatment" doesn't resolve the condition for which medicine is being prescribed when many drugs do resolve a patient's condition thereby permitting the patient to cease taking the medicine. This is particularly true here where Defendants have sought to undermine the traditional medical viewpoint that lifestyle interventions are still considered the first treatment for

obesity, prediabetics, and cardiovascular health. ¶¶ 9, 296-97, 390.

Defendants make a true strawman argument claiming that Plaintiffs "pivot to allege, repeatedly, that Defendants should have provided dietary and general nutritional advice." Br. at 21. While Defendants misstate the allegations in the Complaint, Plaintiffs do allege that Defendants were well aware that the type of weight loss that resulted from patients taking GLP-1 RAs was unhealthy because it resulted in the loss of muscle mass, and if the patient went off the drug, the resulting weight gain would render the patient more unhealthy than they were when they started (*i.e.*, the weight loss was primarily lean muscle, but the inevitable weight regain is fat). *See, e.g.*, ¶¶ 601-08. Despite being aware of this salient fact, Defendants intentionally chose not to convey this information to prescribers, patients, or the general public. ¶¶ 606-07. Instead, they told investors that they would address the problem by developing additional drugs that patients could take to combat the issue. *Id.* In addition, Defendants assert that "Plaintiffs . . . contend that Defendants did not disclose that patients frequently stop taking [GLP-1 RAs] due to adverse events." Br. at 21 (emphasis added). This allegation is taken out of context and misapprehends the core principle of Plaintiffs' allegations that Defendants promote significant weight loss but fail to inform patients that many patients stop taking the drugs, thereby failing to achieve any meaningful weight loss.[12] *See, e.g.*, ¶¶ 609-11. Plaintiffs allege that the failure to disclose this information prevented patients from "factor[ing] that into their analysis of risks and benefits when considering

[12] Defendants ask the Court to take judicial notice of certain 2024 labels claiming that they identify how many patients discontinue using the medications during clinical trials. Br. at 21-22; *see also* Defs.' Req. for Judicial Notice ("RFJN") (ECF 328). The RFJN should be denied for the reasons set forth in Plaintiffs' Opposition thereto filed concurrently with this Response and incorporated herein by reference. In summary, these labels are irrelevant because they do not undermine Plaintiffs' allegations. Among other things, nothing within the labels identifies to prospective patients that the advertised weight-loss is not achieved by a substantial number of patients due to an inability to tolerate a GLP-1 RA. Indeed, the labels do not even appear to reference how many people stop taking the drug.

taking a GLP-1 RA" and "tak[ing] specific steps to mitigate this muscle loss, like dietary changes and strength training." ¶ 608.

Courts have found allegations similar to those made here sufficient to state misrepresentation claims. *See, e.g.*, *Suttman-Villars*, 553 F. Supp. 3d at 962 (denying motion to dismiss because complaint alleged that Defendants made material misrepresentations about the safety and efficacy of the device, the failure rate of the device, and the device's approved uses); *Allergen Biocell*, 537 F. Supp. 3d at 735 (denying motion to dismiss misrepresentation claims because complaint alleged misleading promotional video describing greatly improved safety of procedure while obscuring risk).

Defendants' misrepresentations cannot be construed as unactionable "puffery." Br. at 19-20 (citing *Doe A.F. v. Lyft*, 2024 WL 3497886, at *8 (E.D. Pa. July 19, 2024) (Marston, J.) ("*Lyft*")). In *Lyft*, the Court dismissed misrepresentation claims based on the ride-share's advertisements of "safety for all" and its statements that it will "always treat riders with respect and look out for their safety" because they were "puffery," *i.e.*, commercial exaggeration expressed in broad or vague terms. *Id.* at *7. Here, Plaintiffs' allegations of misrepresentation are based on more than vague terms, but instead go directly to Defendants' knowing exclusion of certain material information and specific misstatements with respect to the safety and efficacy of their products, all with the intent to overstate the benefits and downplay the risks of taking GLP-1 RAs. *See* Sections IV.B.1, IV.B.2, IV.D.2, and IV.B.4 (discussing misrepresentations), *supra*. Intentional deception or actual knowledge about lack of safety or efficacy pushes statements across the line from puffery to active misrepresentations. *See In re Takata Airbag Prods. Liab. Litig.*, 462 F. Supp. 3d 1304, 1318 (S.D. Fla. 2020) (concluding that safety statements were more than mere puffery where manufacturer knew about alleged defect); *In re General Motors LLC Ignition Switch Litig.*, 257 F. Supp.3d 372

(S.D.N.Y. 2017) (concluding that statements about manufacturing "the safest vehicles on earth" were more than puffery when considered with allegations about knowledge of defect); *In re Toyota Motor Corp.*, 2012 WL 12929769, at *18 (C.D. Cal. May 4, 2012) ("Advertising a car as safe and reliable when it actually has a safety-related defect that may render it unable to stop is not 'within the tolerable range of commercial puffery,' especially because Toyota allegedly had exclusive knowledge of the [sudden, unintended acceleration] defect."). Here, Defendants knew about the problems with their GLP-1 RAs, pushing their statements across the line from puffery to active misrepresentations.

5. Plaintiffs Adequately Allege Claims Under Each State's Unfair Trade Practices/Consumer Protection Laws

Count VII alleges claims for violations of the unfair trade practices/consumer protection statutes of approximately 55 jurisdictions, and Plaintiffs identify each statute at issue. ¶ 749. Plaintiffs lay out the core factual allegations that satisfy the elements to support a violation of each statute, and those allegations are supplemented by the voluminous allegations set forth in the remainder of the Complaint. ¶¶ 749-64. Much of the conduct supporting Plaintiffs' claims in Count VII overlaps with the conduct that was discussed with respect to the fraud and misrepresentation claims above. To be clear, contrary to Defendants' suggestion, the elements for violations of the consumer protection laws are pled in Count VII and throughout the Complaint. Br. at 22. It is incumbent upon Defendants, as the moving party, to identify their challenges to these claims.

Defendants' main argument is that to adequately ***brief*** the statutory claims in Count VII, they would be required to research the law interpreting 55 statutes and, instead, Plaintiffs should be required to allege more than facts, identifying specific statutory subsections and relevant case law interpretations at the pleading stage. Br. at 22-23. But the law is clear that Plaintiffs are not required to plead more than the facts that support their claims, and here, they have adequately ***pled***

the claims because they have alleged the appropriate facts. *See, e.g., P.C. of Yonkers, Inc. v. Celebrations! The Party and Seasonal Superstore, LLC*, 2007 WL708978, at *8 (D. N.J. Mar. 5, 2007) ("The notice-pleading standard of Rule 8(a)(2) does not require that a plaintiff plead specific subsections of a statute he or she claims has been violated."); *Berry v. Board of Trustees of University of Illinois*, 2024 WL 809092, at *3 (N.D. Ill. Feb. 27, 2024) ("the Seventh Circuit has been explicit that plaintiffs are not even required to plead specific legal theories, or cite specific statutes at all"); *Alvarez v. Hill*, 518 F.3d 1152, 1157 (9th Cir. 2008) (holding that notice pleading requires a plaintiff to set forth claims for relief, not to cite specific statutes). In an odd twist, Defendants seem to be arguing that Plaintiffs should be forced to make a series of "conclusory allegations" that parrot the language of each of these statutes.

The claims in Count VII simply do not implicate the type of cross-cutting issues that are appropriate for Defendants' Motion and fall squarely within the plaintiff-specific and state-by-state legal issues that the Court should not consider at this time. Defendants concede that this is a jurisdiction-specific issue. Br. at 22-25. Where there are claims from every jurisdiction, Defendants are correct that this requires substantial work and as previously noted, no jurisdiction's law should be short-changed by allowing Defendants to try and capture the nuance of each state's law with a brief list of statutes and cases. *Id*. at 34-35. Each state has developed its own common-law that deserves appropriate attention before the Court makes an *Erie* prediction.

For example, Defendants cite Alabama Code § 8-19-15(a) for the proposition that Alabama's Consumer Protection statute is exclusive of all other claims. Br. at 23. A closer look at the case law, however, reveals that the analysis is more nuanced. In *Bolling v. Mercedez-Benz USA, LLC*, 2024 WL 3972987, at *19 (N.D. Ga. Aug. 27, 2024), the court permitted the plaintiffs to plead their Alabama Deceptive Trade Practices Act claim in the alternative to their fraudulent

concealment claim because "[t]here is substantial conflict in the case law as to whether ADTPA plaintiffs must make 'an election' to pursue a common law or ADTPA claim at the pleading stage or whether they may wait until later in the litigation to decide." Thus, the Court cannot simply read a statute without context and draw an arbitrary conclusion about a particular state's law.

Similarly, Defendants assert that some states bar unfair trade practices claims in the prescription drug context and that others "do not apply to personal injury actions." Br. at 23-24. The problem with this approach, however, is that Defendants cannot simply cherry pick statutes and cases, omit the reasoning of decisions, and demand Plaintiffs' claims be dismissed. In fact, the issues are state-specific and often hinge on an in-depth analysis of a jurisdiction's law. And Plaintiffs cannot do justice in a short opposition brief to the laws of at least 50 unique jurisdictions where the questions may be unsettled and where Defendants have not raised specific issues.

In addition, individual Plaintiffs will assert claims under relevant statutes of the governing jurisdictions. For that reason, this issue should be deferred to bellwether motions practice, likely summary judgment, where the Court can review and fully analyze the law of the governing jurisdiction in the context of specific facts to properly inform the *Erie* analysis.

E. Plaintiffs' Design-Defect Claims Should Proceed

Dismissal of Plaintiffs' design-defect claims (Counts XI and XII) is not appropriate at this time because whether such claims are preempted will turn on the particulars of the applicable state law as well as the specific factual allegations of each Plaintiff. Defendants make essentially two arguments for dismissal: that conflict preemption *per se* bars Plaintiffs' state-law design-defect claims, and that even if it did not, Plaintiffs have not pled facts to state a claim for design defect. But, Defendants do not dispute the recognized exceptions to the preemption principles they rely upon or ignore all of the relevant facts alleged by Plaintiffs that support their design-defect claims. Plaintiffs design-defect claims are not preempted and are adequately pled.

1. Plaintiffs Design-Defect Claims Are Not *Per Se* Preempted

Plaintiffs agree with the general proposition put forth by Defendants—that state-law design-defect claims that would require Defendants to reformulate their drugs to comply with state law will be preempted because the FDA will not normally allow the manufacturer to alter the formulation of its drug without prior agency approval. Br. at 25-27 (citing *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472, 490 (2013)). But, design-defect claims are not preempted under different circumstances.

Most obviously, for example, the Supreme Court explained in *Bartlett* that under many states' laws, design-defect claims may go forward based on design flaws that are inadequately warned of:

> "The duty to warn is part of the general duty to design, manufacture and sell products that are reasonably safe for their foreseeable uses. If the design of a product makes a warning necessary to avoid an unreasonable risk of harm from a foreseeable use, the lack of warning or an ineffective warning causes the product to be defective and unreasonably dangerous" (citation omitted)). Thus, New Hampshire's design-defect cause of action imposed a duty on Mutual to strengthen sulindac's warnings.

570 U.S. at 484 (quoting *Chellman v. Saab-Scania AB*, 637 A.2d 148, 150 (N.H. 1993)).[13] Defendants have already acknowledged that, under *Wyeth v. Levine*, 555 U.S. 555, 573 (2009), product liability claims based on alleged warning deficiencies are not *per se* subject to preemption (because manufacturers may alter warnings without prior approval through the Changes Being Effected process). Br. at 28; *see also In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No.*

[13] New Hampshire is not unique. As the Supreme Court observed: "New Hampshire—like a large majority of States—has adopted comment *k* to § 402A of the Restatement (Second) of Torts, which recognizes that it is 'especially common in the field of drugs' for products to be 'incapable of being made safe for their intended and ordinary use.' Under comment *k*, '[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous.'" *Bartlett*, 570 U.S. at 485 n.2 (internal citations omitted). In these states, defective design will turn on whether the drug was accompanied by adequate warnings.

II), 751 F.3d 150, 159 n.20 (3d Cir. 2014) (noting "impossibility pre-emption was not applicable to design-defect claims against brand-name manufacturers because federal law '. . . provides a mechanism for adding safety information to the label prior to FDA approval'" (citation omitted)).

There are also other circumstances that give rise to non-preempted design-defect claims. ***First***, as *Bartlett* itself highlights, are "state design-defect claims that parallel the federal misbranding statute." 570 U.S. at 487 n.4. As the Supreme Court observed: "The misbranding statute requires a manufacturer to pull even an FDA-approved drug from the market when it is 'dangerous to health' even if 'used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling.'"[14] *Id.* ***Second***, are claims involving a drug promoted for a use for which it has not been approved by the FDA. *See, e.g., In re Testosterone Replacement Therapy Prod. Liab. Litig.*, 430 F.Supp.3d 516, 530-32 (N.D. Ill. 2019). ***Finally***, a plaintiff may assert a viable, non-preempted design defect claim where they allege not only that a defendant's product was unreasonably dangerous, but also that another drug or a different dosage that was already on the market would have been a safer and more effective alternative. *See, e.g., In re Tylenol (Acetaminophen) Marketing*, 2015 WL 7075949, at *14-19 (E.D. Pa. Nov. 13, 2015).

Simply put, design-defect claims are not *per se* preempted.

2. Plaintiffs' Design-Defect Claims Are Adequately Pled

Defendants also assert that Plaintiffs have failed to adequately allege the necessary elements of a design-defect claim even thought they concede that the Complaint "track[s]" every element of such claims. Br. at 29. Defendants focus on a handful of paragraphs that they label as

[14] The Supreme Court noted that "a drug is misbranded under federal law only when liability is based on new and scientifically significant information that was not before the FDA." *Bartlett*, 570 U.S. at 485. No such allegation was made in *Bartlett*, but Plaintiffs here contend that Defendants had such information that was not considered by the FDA. ¶¶ 438-45, 454-587.

"conclusory," Br. at 29-30 (citing ¶¶ 807, 810, 811), while ignoring the mountain of facts alleged by Plaintiffs throughout the Complaint regarding Defendants' knowledge of the defect, deception regarding the risk benefit analysis of taking GLP-1 RAs, adverse effects, etc., *e.g.*, ¶¶ 155-256, 403-30, 434-612. Defendants really seem to be arguing that Plaintiffs have not alleged facts that prevent their design-defect claims from being preempted. But this is not true. Plaintiffs allege that Defendants' GLP-1 RAs were: (1) dangerous to health due to their inadequate label warnings, *e.g.*, ¶¶ 434-587, 806-11, 818-23; (2) misbranded and dangerous to health even if used as suggested, *e.g.*, ¶¶ 266-67; 155-256; and (3) promoted for off-label use (*i.e.*, a use for which it has not been approved by the FDA), *e.g.*, ¶¶ 6-7, 10-11, 266-67, 285-87, 351, 385, 403-15. In addition, whether Defendants' GLP-1 RAs were unreasonably dangerous, and a different drug or dosage on the market would have been a safer and more effective alternative, is an open factual question because the Complaint is replete with allegations regarding additional GLP-1 RAs. Given the variety of GLP-1 RAs on the market and the availability of different forms of semaglutide, liraglutide, and tirzepatide at different dosage levels, individual Plaintiffs may plausibly claim that the particular form of the drug prescribed to them was unreasonably dangerous as compared to other reasonable alternatives. Such issues can only be resolved in the context of a particular (bellwether) complaint under a particular state's law.

Finally, Defendants once again claim that Plaintiffs' allegations of wrongdoing "do not distinguish between the two Defendants." Br. at 29. The flaws in this argument are addressed generally in Section IV.D.2, *supra*. The argument fails here as well. *See, e.g.*, ¶¶ 107-39, 276-86, 289-90, 298-99, 312, 318-21, 463-68, 590-67, 606, 612 (Novo); ¶¶ 140-54, 287-88, 291-92, 299-302, 313, 322-26, 469-74, 590-97, 607, 612 (Lilly). Each Defendant cannot seriously claim to be unaware of the allegations being made against them.

F. Plaintiffs Properly Allege Negligence

Contrary to Defendants' assertions, the Complaint adequately states a claim for negligence in Count XIII. Plaintiffs identify multiple ways in which Defendants' conduct was negligent. *E.g.*, ¶ 834(a)-(m). Notably, Defendants do not argue that Plaintiffs' negligence claim is not recognized by law. Br. at 15. Instead, Defendants question whether Plaintiffs can pursue recovery for more than one manner of negligence in a single count. Br. at 15. Defendants cite no authority that would preclude Plaintiffs from such a pleading.[15] *See generally Tompkins v. Cent. Laborers' Pension Fund*, 2009 WL 3836893, at *3 (C.D. Ill. Nov. 16, 2009) (collecting cases holding that distinct legal claims may be combined in a single count).

Beyond that, Defendants focus on the adequacy of Plaintiffs' allegations with respect to the "purported acts and omissions."[16] Br. at 30–31. While Defendants argue that a single allegation is conclusory, Br. at 30 (citing ¶ 834), they curiously ignore the nearly 600 paragraphs of factual allegations supporting paragraph 834. In fact, the Complaint includes over 100 pages of detailed allegations specifying Defendants' negligent conduct—including with respect to design defect, failure to warn, marketing, testing, and inspection. *See, e.g.*, ¶¶ 29–612.

Plaintiffs explain in great detail the available scientific knowledge regarding the risks of Defendants' drugs—including the studies available as well as the specific testing employed by Defendants and the deficiencies of the same. ¶¶ 155–256. For example, Plaintiffs allege that "Defendants' evaluation of gastrointestinal risks during clinical trials was inadequate" because

[15] Defendants' citation to case law stating the unremarkable position that products liability law typically involves claims of manufacturing defect, design defect and failure to warn is of little help to the Court. Br. at 30. It is fundamental that a plaintiff may assert all of their claims against a defendant arising from the same course of conduct in a single pleading. *E.g.*, FRCP 18.

[16] Defendants focus on whether the "acts or omissions" constituting the breach of a duty have been adequately pled but do not challenge whether they owed a duty or whether any alleged breach of that duty caused harm to Plaintiffs, all elements that have been adequately pled. *E.g.*, ¶¶ 827-41.

"Defendants repeatedly failed to take steps necessary to re-analyze clinical trial data to assess the gastrointestinal side effects of GLP-1 RAs." ¶ 162. Indeed, "neither Novo nor Lilly assessed gastric emptying of solids during their clinical trials [and a]s a result, Defendants' clinical trials . . . were not adequately designed to assess for gastroparesis." ¶ 164. Plaintiffs allege how a member of the advisory boards for both Lilly and Novo acknowledged these flaws in the clinical trials. ¶ 165.

In addition, the Complaint details the regulatory framework with which Defendants must comply, ¶¶ 257–75, the pervasive marketing efforts of Defendants, ¶¶ 276–430, the ways in which Defendants breached their duties, ¶¶ 162–65, 434–612, and the resulting harms to Plaintiffs, ¶¶ 41–95. Taken together, the Complaint easily satisfies the threshold of plausible allegations for a negligence claim.[17]

Finally, Defendants have neither asserted that any particular theory of negligence is unavailing nor provided support for such an argument.[18] Accordingly, Defendants have not adequately raised this argument in their Motion sufficient for Plaintiffs to respond and, therefore, the Court should refrain from ruling on any particular theory of negligence. Indeed, the relevant negligent conduct may differ in each case based on the specific drug or advertisement at issue and/or the variations in state law that will be set forth by each Plaintiffs in their Short Form Complaint further illustrating why the Motion should be denied at this time.

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[17] The cases relied upon by Defendants are inapposite as they involve merely conclusory allegations, *i.e.*, plaintiff was "negligent," without the detailed factual background and specificity present here. *See Ramos-Soto v. C.R. Bard, Inc.*, 2022 WL 1056581, at *1 n.i (E.D.P.A. Jan. 14, 2022) (plaintiffs solely made conclusory allegations that defendant was "negligent"); *see also Cerniglia v. Zimmer Inc.*, 2017 WL 4678201, at *3 (D.N.J. Oct. 17, 2017) (no claim under New Jersey's Product Liability Act where plaintiffs merely alleged device was "defective").

[18] Defendants' suggestion that the Court should strike the negligence count to the extent it includes negligent failure to warn is a red herring. Br. at 31. The negligence alleged in Count XIII is more far-reaching and distinct from Plaintiffs' negligent failure to warn claim set forth in Count I.

G. Plaintiffs Plausibly Allege a Claim for Negligent Undertaking

Plaintiffs allege how Defendants engaged in an extensive and multi-faceted marketing campaign with the intent to create and grow a market for their GLP-1 RAs. ¶¶ 276-433. The Complaint lays out in detail Defendants' direct-to-consumer marketing efforts. *See* ¶¶ 370-433; *see also* ¶¶ 842-62. These direct-to-consumer efforts were so successful that Novo acknowledged that a large portion of the increase in GLP-1 RA prescriptions was "driven by patients." ¶ 846. This conduct forms the basis for Plaintiffs' negligent undertaking claim in Count XIV. ¶¶ 842-62.

In detail, Plaintiffs allege that Defendants' decision to conduct extensive direct-to-consumer advertising campaigns demonstrates a voluntary assumption of a responsibility to communicate safety information directly to consumers. *See, e.g.*, ¶¶ 276–308, 370–415. Plaintiffs allege the Defendants spent over a billion dollars to market their drugs to consumers directly via branded and unbranded advertising on television, social media, and other online platforms—including using celebrity spokespersons and buying ads during significant viewership moments like the Super Bowl and the Olympics. ¶¶ 373–74, 379, 382–84, 392–402. Novo's conduct was so pervasive that Ozempic became a household name, was declared "2023's buzziest drug," and was so ubiquitous that it become a favorite topic of jokes at very public events such as the Oscars. ¶ 371; *see* ¶¶ 370–72, 375–77. Lilly took a similar approach partnering with influential people to market their drugs directly to their followers on social media—conduct far beyond that of a "normal" prescription drug advertisement. ¶¶ 381, 383. Through its branded, unbranded, and targeted advertising, Defendants specifically and intentionally expanded demand for its drugs and these efforts were so successful that they resulted in shortages of the drugs, "redefin[ing] what big looks like in drug sales." ¶¶ 370–402, 289–92. Indeed, patients started to drive demand. *E.g.*, ¶ 846 (Novo noting that "a big part of the prescriptions are driven by patients[.]").

Through these actions, Defendants assumed a duty of care to consumers. Their direct-to-

consumer campaigns created an independent, actionable duty to the consumers who viewed and relied upon the advertisements to their detriment. *See, e.g.*, ¶¶ 843–44. Instead of adequately satisfying this duty, Defendants omitted material information and misled consumers regarding the associated risks of harm. *See, e.g.*, ¶¶ 372, 376, 735–37, 770–75, 751, 782, 849–56. Plaintiffs relied on Defendants' advertisements to seek out prescriptions for Defendants' drugs and were harmed as a result. *See, e.g.*, ¶¶ 761–62, 783–84, 786–87, 798, 800–02, 857–62. Thus, Defendants' failure to satisfy the duty they undertook is actionable. *See, e.g., Fox v. Amazon.com, Inc.*, 930 F.3d 415, 426-28 (6th Cir. 2019) (analyzing elements of plaintiffs' negligent undertaking claim and reversing dismissal by district court).

Defendants make two flawed arguments for dismissal of Plaintiffs' negligent undertaking claim—that courts purportedly "have rejected negligent undertaking in the context of prescription medicines" and an otherwise generalized failure to adequately plead the claim.[19] As set forth below, both of these arguments should be rejected. In addition, Defendants' argument should be rejected because, as they acknowledge, the viability of a claim for negligent undertaking varies by jurisdiction, Br. at 32 ("*Perez* is an outlier opinion that many other state courts have declined to follow."), and 33 ("some state courts have rejected application of negligent undertaking in product liability cases absent unique facts that are not pleaded here"); and the applicability of a negligent

[19] Defendants' characterization of Plaintiffs' negligent undertaking claim as "an obvious but inadequate attempt to plead around the learned intermediary doctrine" says nothing about whether Plaintiffs have adequately stated a claim. Br. at 31. In addition, not every jurisdiction has adopted the learned intermediary doctrine, and even when it does apply, its applicability turns on the facts particular to each plaintiff. *See, e.g., Butler v. Juno Therapeutics, Inc.*, 2019 WL 2568477, at *16-19 (S.D. Tex. June 21, 2019) (court declining to decide whether to impose an exception to the learned intermediary doctrine at the motion to dismiss stage). In addition, there are a number of exceptions to the learned intermediary doctrine that are implicated by the allegations in Plaintiffs' Complaint, including overpromotion to doctors. *E.g.*, *Boehm v. Eli Lilly & Co.*, 747 F. 3d 501, 508 (8th Cir. 2013) (discussing overpromotion exception).

undertaking claim depends upon facts specific to each Plaintiff.

1. Plaintiffs' Factual Allegations Support a Negligent Undertaking Claim

Under the Restatement (Second) of Torts, § 323,[20] an individual or entity that undertakes to perform a service or provide warnings to another assumes a duty to that person to exercise reasonable care in carrying out that undertaking. That section recognizes that, once such a duty is assumed, the undertaking party can be held liable if his failure to exercise care increases the risk of harm ***or*** if harm is suffered because of the plaintiff's reliance upon the undertaking. Restatement (2d) of Torts § 323. *See also id.* at § 324A.[21]

The theory of negligent undertaking is an independent theory of liability that arises from a defendant's voluntary assumption of a duty. This duty is independent of any defect in the product itself. Defendants' voluntary representations to consumers—in this case via their advertising—creates an obligation that, if breached, constitutes negligence. Here, Plaintiffs' argument is not that Defendants undertook a duty to warn all consumers directly simply because they sold a product, but instead, ***by choosing to market their drugs directly to the consumer***, they engaged in voluntary conduct that assumed such a duty.

The Third Circuit has recognized a theory of negligent undertaking; adopting the Restatement's formulation and noting that a right to recover could exist under either a theory of

[20] Section 323 provides:"[o]ne who undertakes, gratuitously . . . to render services to another which he should recognize as necessary for the protection of the other's person . . . is subject to liability to the other for physical harm resulting from his failure to exercise reasonable care to perform his undertaking, if (a) his failure to exercise such care increases the risk of such harm, or (b) the harm is suffered because of the other's reliance on the undertaking." Restatement (2d) of Torts § 323.

[21] Section 324A focuses on the harm to a third person, while § 323 addresses harm to the person who received the services. *See* Restatement (2d) of Torts §§ 323, 324A. Accordingly, while § 324A also describes a claim of negligent undertaking, the facts here more appropriately fall within § 323 because the person who saw the direct-to-consumer advertisement and sought a prescription on that basis is also the person who was harmed.

detrimental reliance or increased risk of harm. *See Patentas v. United States*, 687 F.2d 707, 714-16 (3d Cir. 1982). The Third Circuit has also noted that a claim of negligent undertaking could lie if a plaintiff alleged that a defendant undertook the responsibility to warn of certain risks but failed to do so. *See Sheridan v. NGK Metals Corp*., 609 F.3d 239, 263–64 (3d Cir. 2010).[22] Other courts, such as the Sixth Circuit, have upheld a claim of negligent undertaking in a products liability case, where the defendant reached out to the consumer directly to provide a warning, and that warning was deficient. *See, e.g.*, *Fox*, 930 F.3d at 426-27 (upholding claim for negligent undertaking relying on §§ 323 and 324A, as well as Tennessee law).[23]

The case cited by Plaintiffs in the Complaint and discussed by Defendants, *Perez v. Wyeth Labs, Inc*., 734 A.2d 1245 (N.J. 1999), illustrates that the principles of § 323 apply with equal force in the context of direct-to-consumer marketing of prescription medications. 734 A.2d at 1258-59. While Defendants assert that *Perez* does not concern a "claim" of negligent undertaking, Br. at 32, they ignore that the analysis undertaken by the New Jersey Supreme Court is analogous to a theory of negligent undertaking because the question there was whether, by virtue of its direct-to-consumer marketing, the defendant had a duty to warn the consumer directly. *See, e.g.*, *Perez*, 734 A.2d at 1255-56. Indeed, the court in *Perez* evaluated the policies underlying the learned intermediary doctrine and determined that "direct marketing of drugs to consumers generates a corresponding duty requiring manufacturers to warn of defects in the product."[24] *Id*. at 1263-64.

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[22] In that case, however, the court found that plaintiffs' complaint was lacking in that it failed to allege that defendants undertook the responsibility of making a warning. *Sheridan*, 609 F.3d at 263–64. Here, however, Plaintiffs have included such allegations. *See, e.g.*, ¶¶ 843–48. Additionally, while *Sheridan* considered the application of § 324A, that section is analogous to § 323 with respect to engaging in conduct that is deemed to voluntary assume a duty. *See* Restatement (2d) of Torts §§ 323, 324A.

[23] *See also State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 909-913 (W. Va. 2007) (discussing impact of direct-to-consumer marketing on manufacturer's duty to warn).

[24] One justification for the learned intermediary doctrine is an inability to warn the customer due

Defendants do not cite a case for the broad proposition that there is a *per se* prohibition against negligent undertaking claims in the context of prescription medications. Instead, Defendants cite a handful of cases where a court declined to adopt § 323 and/or where the facts would not have supported such a claim. *See, e.g.*, *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 162-63 (Tex. 2012) (Court considered the direct-to-consumer marketing exception to the learned intermediary doctrine but noted that it was inapplicable to the facts of the case because the plaintiff saw the advertisement ***after*** the prescription and ***after*** she began the drug infusion).[25] Defendants have not challenged a negligent undertaking claim under any specific jurisdiction's law, and

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to a lack of direct communication with patients, which is obviously absent in a direct-to-consumer marketing scenario. By speaking directly to consumers through advertising, pharmaceutical companies not only have the opportunity, but also the obligation, to properly explain the risks. Allowing companies to profit from these interactions while at the same time insulating them from liability for failure to warn is incongruous. Should pharmaceutical companies choose to engage in direct-to-consumer marketing, they should likewise shoulder an accompanying duty to warn. On the other hand, if pharmaceutical companies wish to avoid warning the consumer directly, they need not engage in such marketing tactics.

[25] *See, e.g.*, *Watts v. Medical Pharm. Corp.*, 365 P.3d 944, 950-52 (Ariz. 2016) (No allegation that direct-to-consumer advertising resulted in the plaintiff asking for a particular prescription. Instead, the allegations concerned publications her physician gave her with the prescription.); *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376 (S.D. Fla. 2007) (No allegation that doctor was specifically influenced by defendants' marketing); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 759-60 (Ky. 2004) (doctor prescribed sample package to plaintiff without any request from the patient for a specific drug or mention of an advertisement seen by plaintiff that caused him to seek that prescription); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practice and Prods. Liab. Litig.*, 226 F. Supp. 3d 557, 580 n.12 (D.S.C. 2017) (generally discussing Pennsylvania case law regarding § 323 but granting defendant's motion for summary judgment because the plaintiffs lacked a causation expert); *Nichols v. McNeilab, Inc.*, 850 F. Supp. 562, 569 (E.D. Mich. 1993) (§§ 323 and 324 not discussed; instead, question was whether the learned intermediary doctrine protected a manufacturer from issuing a warning following a post-market removal, and the court found that the learned intermediary did not apply). The court in *Moretti v. Wyeth, Inc.*, 2009 WL 749532 (D. Nev. Mar. 20, 2009) found that Nevada law did not support a negligent undertaking claim, but here the allegations are different because Plaintiffs specifically ***sought prescriptions*** based upon the misleading direct-to-consumer marketing by Defendants. *Compare* 2009 WL 749532, at *3 (no allegations of direct-to-consumer marketing to plaintiff that resulted in the prescription) *with* ¶ 846 ("a big, big part of the prescriptions are driven by patients asking") and ¶ 857 ("[Plaintiffs] would not have sought a prescription for the Defendants' weight loss drugs").

Plaintiffs should not be made to take on a jurisdiction-by-jurisdiction analysis that would amount to merely a guess of Defendants' position. Nor would such an analysis be consistent with the purported cross-cutting purposes of Defendants' Motion. It is essential for this Motion that there is no prohibition against a negligent undertaking claim in the context of prescription drugs.

Given Defendants' gratuitous undertaking to provide warnings directly to consumers, a negligent undertaking claim is entirely applicable. Here, reading the allegations in the light most favorable to Plaintiffs, the complaint states a plausible claim that Defendants voluntarily undertook a duty to warn consumers and their failure to properly discharge that duty resulted in harm.

2. State Law Variation and Related Fact-Specific Inquiries Illustrate that Negligent Undertaking Is Not the Type of Cross-Cutting Issue Appropriate for this Motion

As noted above, Defendants' arguments rely exclusively on applications of varying state law. Br. at 31-33. That alone counsels in favor of denying their Motion. However, the state law variations with respect to negligent undertaking are also driven largely by fact-specific inquiries. For example, whether Plaintiffs sought prescriptions based on specific advertisements is a significant consideration in whether a valid claim exists. *See, e.g., Centocor, Inc.*, 372 S.W.3d at 162-63 (court considered the direct-to-consumer marketing exception to the learned intermediary doctrine but noted that it was inapplicable to the facts of the case because the plaintiff saw the advertisement ***after*** the prescription and ***after*** she began the drug infusion); *Ideus v. Teva Pharms. U.S., Inc.*, 986 F.3d 1098, 1103 n.4 (8th Cir. 2021) (noting that, even if the direct-to-consumer marketing exception was embraced, a magazine advertisement postdating the implant by six years would not qualify). Because of the state-specific and fact-specific nature of the voluntary undertaking claim, Defendants' arguments—to the extent they have any merit at all—should be considered in the context of a specific bellwether case and the contours of the pertinent state's law.

H. Plaintiffs Have Adequately Preserved State Product Liability Act Claims

A handful of states have passed PLAs that provide an exclusive, or near exclusive, means of asserting products liability claims.[26] In some of those states, the law requires that any theory of product liability be brought under the state PLA, meaning that instead of pleading various causes of action (*e.g.*, breach of warranty, fraud, etc.), the plaintiff simply brings an action for violation of the PLA and within that claim, the plaintiff can assert multiple theories of recovery. *See, e.g.*, *LaMontagne v. E.I. Du Pont De Nemours & Co.*, 41 F.3d 846, 855-56 (2d Cir. 1994) (CPLA not intended "to eliminate common-law substantive rights," but instead "merged [them] into one cause of action which has been created by statute."); *Knoth v. Apollo Endosurgery US, Inc.*, 425 F. Supp. 3d 678, 687 (S.D. Miss. 2019) (MPLA providing exclusive remedy "does not mean that common law negligence or breach of implied warranty claims are disallowed"). While some of the state PLAs subsume, or perhaps prohibit, some of the claims brought by Plaintiffs, most permit some claims to proceed alongside a PLA claim. *See, e.g.*, *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, 2021 WL 364663, at *13 (D.N.J. Feb. 3, 2021) (state consumer protection statutes and breach of express or implied warranty found not to be subsumed by Indiana PLA).[27]

Importantly, Plaintiffs have alleged facts that support all of the causes of action that would be subsumed as theories within any given state PLA claim. *See* Sections IV.A through IV.G, *supra*.

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[26] Conn. Gen. Stat. § 52-572M, *et seq.*; Ind. Code § 34-20-1-1; Kansas Stat. Ann. 60:3301, *et seq.*; La. Stat. Ann. § 9:2800.51, *et seq.*; Miss. Code Ann. § 11-1-63; N.C. Gen. Stat. § 99B-1.1; N.J. Stat. Ann. 2A:59C; Ohio Rev. Code § 2307.72(A) & (B); Tenn. Code Ann. § 29-28-101, *et seq.*; Wash. Rev. Code Ann. § 7.72.010, *et seq.*

[27] *E.g.*, *Mattos v. Eli Lilly & Co.*, 2012 WL 1893551, at *2 (D. Kan. May 23, 2012) (KCPA claims not subsumed by KPLA); *Valsartan*, 2021 WL 364663, at *7 & n.4 (express warranty and NJCFA claims not subsumed by NJPLA); *Hollar v. Philip Morris Inc.*, 43 F. Supp. 2d 794, 808-09 (N.D. Ohio 1998) (common law fraud not subsumed by the OPLA); *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 943 (S.D. Ohio 2010) (UCC breach of warranty not subsumed by OPLA); *Valsartan*, 2021 WL 364663, at *19 (state consumer protection not subsumed by TPLA); *Cutter v. Biomet, Inc.*, 2019 WL 2450785, at *1 (W.D. Wash. June 12, 2019) (fraud not subsumed by WPLA).

Tellingly, Defendants do not assert that a state's PLA requires Plaintiffs to assert additional facts. Within each substantive cause of action, Plaintiffs alleged that they "intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act." ¶ 647; *see* ¶¶ 705, 727, 746, 763, 785, 799, 812, 824, 839, 860, 868, 872, 876. This allegation was intended to put Defendants ***on notice***—when that paragraph appears within a claim (*e.g.*, breach of implied warranty) then an individual Plaintiff whose claims are covered by a state PLA will assert that claim (*e.g.*, breach of implied warranty) in their state PLA claim, if permitted, or will check the "breach of implied warranty" claim as a separate Count if such claim is not subsumed. That satisfied Plaintiffs' pleading burden. *See, e.g.*, *Berry*, 2024 WL 809092, at *3 ("the Seventh Circuit has been explicit that plaintiffs are not even required to plead specific legal theories, or cite specific statutes at all"); *Alvarez*, 518 F.3d at 1157 (holding that notice pleading requires a plaintiff to set forth claims for relief, not to cite specific statutes).

The entire basis for Defendants' Motion with respect to state PLAs is the need to analyze the wide variation in state law. Defendants once again ignore that individual Plaintiffs will file a Short Form Complaint in which they will identify their individual facts, the causes of action they are incorporating from the Master Complaint, and any additional causes of action they assert. Defendants' claim that the current Complaint "cause[s] confusion" is unsupported and there is no efficiency to be gained by requiring each state's PLA be pled as a separate Count at this time, Br. at 35-36, because it would not result in dismissal of any claims nor would it change the scope of the discovery required. This is simply a Plaintiff-specific, fact-specific and state law-specific issue that should not be addressed on this Motion.

Defendants' remaining arguments are a strained attempt to convert their individual state-

law arguments into a heightened pleading standard. Defendants ask the Court to require Plaintiffs to file a new Complaint "to plead state-specific requirements," but do not identify any requirements that are deficient; or they request that Plaintiffs provide up to 20 different versions of a Short Form Complaint so they can engage in the very state-specific motion process that the Parties agreed to defer. Br. at 36. In addition, with respect to the few states' laws that Defendants identified in passing, they do not involve subsumption nor do not require special pleading. Br. at 34-35 & n.9 (Alabama, Michigan and Texas). Instead, Defendants' arguments reflect that these states' laws involve what they believe to be helpful presumptions or defenses. Defendants' requested relief seeks to turn their nuanced state law arguments into a mandate from the Court that Plaintiffs guess what elements of their claims Defendants believe are subject to potential defenses and in which states, and then amend their pleading based upon that guess—this is clearly inappropriate.

I. Plaintiffs' Request for Medical Monitoring Relief Is Appropriate

Plaintiffs have a right to be made whole and it is proper to seek compensation for any medical monitoring they require to prevent exacerbation of their injuries or additional injuries resulting from their use of Defendants' GLP-1 RAs. *See, e.g., Metro–North Commuter R.R. Co. v. Buckley*, 521 U.S. 424, 438-39 (1997) ("The parties do not dispute—and we assume—that an exposed plaintiff can recover related reasonable medical monitoring costs if and when he develops symptoms."). In addition to noting the unremarkable position that damages cannot be speculative, Defendants' argument relies primarily on the fact that different states handle medical monitoring differently: some require that Plaintiffs already have a "manifest" or "present" physical injury; and according to Defendants, some states require Plaintiffs allege they have a "significantly" increased risk of contracting a latent disease. Br. at 36-37. Defendants offer no *Erie* analysis of the relevant state's laws and make no specific challenges. This issue should not be decided at this time.

Substantively, it is true that the law on medical monitoring varies greatly by jurisdiction

but that is based primarily on two factors: (1) whether a plaintiff needs to already have a present (or manifest) physical injury to seek medical monitoring relief (and relatedly, whether subcellular injury can satisfy the present physical injury requirement); and (2) whether medical monitoring can be brought as its own independent claim (rather than simply a form of relief). *See Exxon Mobile Corp. v. Albright*, 71 A.3d 30, 74-78 (Md. 2013) (discussing background of medical monitoring). Defendants' argument is misguided because this MDL is comprised only of personal injury cases meaning that ***every*** Plaintiff who seeks medical monitoring damages will already have a "manifest" or "present" physical injury (the injury is not "latent"), and as to the second issue, Plaintiffs are only seeking medical monitoring as a remedy, not as an independent cause of action. For these reasons, the cases relied upon by Defendants completely miss the mark. *See, e.g.*, *Sinclair v. Merck & Co.*, 948 A.2d 587, 591, 595 (N.J. 2008) (plaintiff must allege physical injury to recover the costs of medical monitoring); *Lowe v. Philip Morris USA, Inc.*, 183 P.3d 181, 184-85 (Or. 2008) (medical monitoring not available where "Plaintiff has not alleged that her exposure to defendants' products has resulted in any present physical effect, much less any present physical harm."); *Exxon Mobile Corp.*, 71 A.3d at 78-79 (decided after full jury trial, no physical injury required so needed to show "significantly" increased risk of contracting latent disease ***based on level of exposure***); *see also Bryson v. Pillsbury Co.*, 573 N.W.2d 718, 721-22 (Minn. Ct. App. 1998) (at summary judgment, plaintiff ***had not produced evidence*** of potential future harm to move damages beyond speculative). Defendants' challenge to the inclusion of medical monitoring relief should be denied.

V. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court deny the Motion to Dismiss. To the extent the Court is inclined to grant any part of the Motion, Plaintiffs request they be given an opportunity to amend the Master Complaint to cure any identified deficiencies.

Dated: March 18, 2025

Respectfully submitted,

/s/ Paul J. Pennock

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CERTIFICATE OF SERVICE

I hereby certify that on March 18, 2025, a true and correct copy of Plaintiffs' Response in Opposition to Defendants' Motion to Dismiss Plaintiffs' Master Complaint, along with the accompanying exhibits and proposed order, was electronically filed using the Court's CM/ECF System, which will send notification of such filing to all counsel of record, and is available for viewing and downloading from the ECF System.

Dated: March 18, 2025

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